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Dear Colleague

ABORTION – APPROVAL EXTENSION FOR MIFEPRISTONE TO BE TAKEN AT HOME

Purpose

1. At the onset of the pandemic a new temporary approval was granted by the Scottish Ministers[1], which has allowed both stages of early medical abortion treatment to be undertaken in a patient's home in certain circumstances. The primary purpose of this letter is to notify you that the Scottish Ministers have granted an updated approval which extends this provision. This letter also contains updated guidance on provision of anti-D for certain patients and also asks staff to ensure continuing caution when applying the existing guidance.

Updated early medical abortion at home approval

2. The approval granted in March 2020 for early medical abortions at home (EMAH) has allowed both misoprostol and mifepristone to be taken in a patient's home if the patient wished, following on from a telephone or video consultation where a doctor or nurse decided that was clinically appropriate for the patient. The approval was granted based on the risk of coronavirus transmission and the need at the time to minimise numbers of patients attending clinics in person. As restrictions have now eased, the Scottish Ministers have reviewed the approval, and agreed an updated version that allows the arrangements for early medical abortions at home to continue, at least for the time being. Arrangements will be reviewed once the current evaluation of EMAH, led by NHS Lothian, is completed.

3. The updated approval has removed the requirement for the coronavirus to be a considered serious and imminent threat to public health in order to allow mifepristone to be taken at home following either an in person clinic appointment, or a telephone or video consultation.

4. In addition, the new approval also allows for doctors to prescribe abortion medication from home. This change has

From the Chief Medical Officer
Professor Sir Gregor Smith

8 June 2022

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Addresses
For action
Territorial NHS Board Chief Executives
NHS Abortion Leads

For information
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[1] See Abortion: Covid-19: Approval for Mifepristone to be taken at home and other contingency measures (scot.nhs.uk)

been made to ensure it is clear that this is permissible and provide flexibility for NHS Boards, particularly if doctors are able to work, but need to self-isolate.

5. For completeness, the new approval will also continue to permit the taking of misoprostol at home after taking mifepristone in a clinic. The previous approval of March 2020 has now been revoked.

6. A copy of the signed approval is provided at **Annex A**.

7. The Scottish Abortion Care Providers (SACP) network has previously produced clinical guidance that all professionals are expected to follow when considering this treatment option for patients. A copy of this existing March 2020 guidance is provided at **Annex B** and this remains in place.

8. However, given the easing of restrictions, and following advice from the Scottish National Blood Transfusion Service, in line with paragraph 6 of the existing guidance, I am recommending that for patients that are between 10 weeks and 11+6 weeks' gestation, are now routinely encouraged to have **anti-D** if their blood group is rhesus D negative. Therefore, unless there is a significant worsening of the pandemic (and associated change in public health advice), patients of 10 weeks or over whose blood group is unknown or those who are rhesus D negative, should now normally be required to attend at least one in person clinic appointment. This will allow for anti-D to be administered if required, and is in-keeping with the 2019 NICE guidance[2] on this.

9. In addition, while the approval has been extended, I would ask Boards to continue to be vigilant when offering this service to women. In particular, where a woman may be unsure of the gestation of the pregnancy or in circumstances where there are indications that a woman may be vulnerable. In such circumstances the Board should consider whether the woman should be asked to attend clinic/hospital for an ultrasound scan, and/or providing support for them to take their medication(s) in the clinic/hospital. I would also ask that staff continue to ensure that women are aware that having an abortion at home at a later gestation could potentially put them at higher risk and so it is important that they say so if they are in any way unsure about the date of their last period.

10. **The updated approval is now in effect as from 13 May 2022**.

Action

11. Chief Executives of NHS Boards are responsible for ensuring that relevant staff are notified of the above changes, this includes all abortion service and Fetal Medicine staff, and pharmacy staff. All Boards should consider whether changes to procedures are required to allow for early medical abortions at home to continue to be made available to women, and for the reintroduction of in clinic appointments for women of 10 weeks gestation and over where their blood type is unknown or who are rhesus negative.

Yours sincerely,

Gregor Smith

Professor Sir Gregor Smith
Chief Medical Officer

[2] See section 1.3 - Recommendations | Abortion care | Guidance | NICE

The Abortion Act 1967 (Place for Treatment for the Termination of Pregnancy) (Approval) (Scotland) 2022

The Scottish Ministers make the following approval in exercise of the powers conferred by section 1(3) and (3A) of the Abortion Act 1967[1], and all other powers enabling them to do so.

Commencement

1. This approval comes into force on the day after the day on which it is made.

Interpretation

2. In this approval—

"approved place" means a hospital in Scotland, as authorised under section 1(3) of the Abortion Act 1967 or a place in Scotland approved under that section;

"home" means—

(a) in the case of a pregnant woman, the place in Scotland where a pregnant woman is ordinarily resident;

(b) in the case of a registered medical practitioner, the place in Scotland where a registered medical practitioner is ordinarily resident;

"pregnancy" and "pregnant woman" are to be construed by reference to the Abortion Act 1967.

Approval of class of place

3. The home of a registered medical practitioner is approved as a class of place for treatment for the termination of pregnancy for the purposes only of prescribing the medicines known as mifepristone and misoprostol to be used in treatment carried out in the manner specified in paragraph 6.

4. The home of a pregnant woman who is undergoing treatment for the purposes of termination of her pregnancy is approved as a class of place for treatment for the termination of pregnancy where that treatment is carried out in the manner specified in either paragraph 5 or paragraph 6.

5. The treatment must be carried out in the following manner—

(a) the pregnant woman has attended an approved place (other than her home) where she has been prescribed mifepristone and misoprostol to be taken for the purposes of termination of her pregnancy; and

(b) the pregnant woman has taken mifepristone at that place and wants to take the medicine known as misoprostol at home.

[1] c. 87. Section 1(3A) was inserted by section 37(3) of the Human Fertilisation and Embryology Act 1990 (c. 37).

6. The treatment must be carried out in the following manner—

(a) the pregnant woman has had a consultation with a registered medical practitioner or registered nurse acting under the direction of a registered medical practitioner by means of video link or telephone;

(b) a registered medical practitioner has prescribed the pregnant woman mifepristone and misoprostol to be taken for the purposes of termination of her pregnancy; and

(c) the pregnant woman—

(i) has attended an approved place (other than her home) where she has taken mifepristone and wants to take the misoprostal at home; or

(ii) wants to take the mifepristone and misoprostol at home.

Revocation

7. The Abortion Act 1967 (Place for Treatment for the Termination of Pregnancy) (Approval) (Scotland) 2020[2] is revoked.

Maree Todd

Authorised to sign by the Scottish Ministers
12th May 2022

[2] Made on 30 March 2020.

Annex B

SCOTTISH ABORTION CARE PROVIDERS (SACP) GUIDANCE

Guidelines for approval of early medical abortion with self-administration of mifepristone and misoprostol in the home setting – COVID-19

Early Medical Abortion at Home (EMAH)

Purpose

The purpose of this document is to provide a guideline, in light of the current COVID-19 pandemic, for the provision of consultation via telemedicine and take-home mifepristone and misoprostol for early medical abortions. Where patients **up to 11 weeks + 6 days gestation** either choose or need (based on current public health advice) to self-administer, at home, rather than at a healthcare facility, or where clinics are not able to see women in person due to COVID-19-related staffing reasons and/or to minimise risk of transmission of covid-19.

The attached Appendix includes guidance from ISD on completion of yellow notification forms for patients treated under this new set of guidelines.

Guidance

If clinics are unable to or feel it would be inadvisable to see women in person due to restrictions and pressures as a result of COVID-19, the following protocol can be applied.

- After consultation by telephone and with verbal consent, the EMAH 'home' package (to be delivered at a defined time to a home address), should include mifepristone, misoprostol, pregnancy test and analgesia, with full written instructions and advice (or where patients are able to access these instructions from the service online, provide the website source), including emergency contact numbers.

- Providers should consider including antibiotics for chlamydia, and a supply of bridging contraception in the package where appropriate.

- The gestation limit should be taken by last menstrual period.

Background

Evidence has clearly demonstrated that early medical abortion with at home self-administration of mifepristone and misoprostol is a safe method of abortion. There is no higher risk of complications than with medical abortions carried out as a day case in hospital.

This offers a choice to women requesting an abortion and, in addition to practical and logistical benefits and reduced risk to patients and staff of COVID-19 disease transmission and avoidance of delays to patient treatment, enables women to complete treatment in an environment where they feel most comfortable.

Women meeting the inclusion criteria will be not be required to attend the clinic for mifepristone administration. They will self-administer both mifepristone and misoprostol at an agreed time interval between the two medications, thus completing treatment without the need for a face to face visit.

Inclusion Criteria

The woman:

- Is certain of the decision to proceed to abortion and wishes to administer both first (mifepristone) and the second part of treatment (misoprostol) at home.
- Fulfils the criteria set out in the Abortion Act 1967.
- Is ordinarily resident in Scotland.
- Does not have symptoms of an ectopic pregnancy (pain/bleeding) or other indication for an ultrasound scan.
- Is ≤11+6 weeks gestation on the day of mifepristone administration (as calculated from the date of the last menstrual period).
- Is 16 years of age or above, unless appropriate supports are in place.
- Has no significant medical conditions or contraindications to medical abortion.
- Is able to understand all information given, and to follow instructions for mifepristone and misoprostol administration.
- Fully understands the need to confirm the success of the procedure in line with local protocols.

Contra-Indications / Caution for mifepristone / misoprostol

Mifepristone and misoprostol should be used with caution in certain conditions. Please refer to the table below:

Absolute contra-indications	**Caution required in the following circumstances (discuss with senior medical staff)**
Inherited porphyria	Woman on long-term corticosteroids
Chronic adrenal failure	Asthma (avoid if severe)
Known or suspected ectopic pregnancy	Haemorrhagic disorder or on anticoagulant therapy
Uncontrolled severe asthma	Prosthetic heart valve or history of endocarditis
Previous allergic reaction to one of drugs involved	Pre-existing heart disease
	Hepatic or renal impairment
	Severe anaemia
	Severe inflammatory bowel disease e.g. Crohns
	IUCD in place (remove pre-procedure)

Day of telemedicine appointment

Appointment can be either by telephone or, where feasible, via video call.

1. Confirm that patient is certain of decision to proceed to abortion, including the self-administration of mifepristone and misoprostol at home. Obtain verbal consent in line with local policy.

2. Advise that the patient may wish to consider having an adult at home with them for support after they self-administer misoprostol. However, during the pandemic, and while public health advice does not permit mixing between households, this should only be if the adult lives in the same household as the patient.

3. Discuss contraception options and provide ongoing contraception in line with national guidelines.

4 If there are symptoms of significant anaemia, advise the patient she will need to have her full blood count (FBC) checked so will need to wait until she can have a clinic appointment at the earliest opportunity. If result confirms severe anaemia, arrange ward admission for misoprostol, and onward investigation and treatment as per local guidance.

5. No STI screening is required, but where the patient is at higher risk of STI, antibiotic treatment for chlamydia should be included in the pack with instructions about taking these.

6. Up to 10 weeks gestation, NICE guidance indicates that no anti-D is required for medical abortions. For those patients over 10 weeks, but under 11 + 6 weeks, whilst there is no strong evidence that anti-D is not necessary, there is also no evidence that it is needed. During the current period, the evidence suggests that the subsequent risks for rhesus negative patients of not receiving anti-D are likely to be very low and much smaller than the risk of exposure to and health impacts from covid-19 if the patient travels to clinic unnecessarily. On that basis, during the covid-19 outbreak only, no anti-D is required for these patients if they would not otherwise need to travel to a clinic.

7. Advise that the patient should administer 200 mg mifepristone orally. Advise the patient that if vomiting occurs within 2 hours then she should contact the clinic as mifepristone dose will need to be repeated.

8. Obtain home address where the take-home pack of mifepristone, misoprostol and analgesia can be delivered, in line with local policy and agree timing period for delivery. The patient should be advised on arrangements for delivery – the person leaving the package should leave it on the doorstep and will not need to take any signature, but will ring the door bell and want confirmation that the person is there to receive it (e.g. particularly if the person has or may have covid-19 they should not open the door while the delivery person is there, but could wave through the door or a window or answer a phone call to confirm that the package will be received by the correct person). The patient should also be advised to get in touch if they have not received the package within a few hours after the agreed time. While ideally providers should arrange delivery wherever possible, where this is not feasible, providers can use Royal Mail for delivery, but should ensure packages are sent special or recorded delivery.

9. Dispense prophylactic antibiotics for the at home package, if required, in line with local policy. The home package should also contain analgesia, bridging contraception if required and the pregnancy test to confirm success of the procedure.

10. Dispense take–home pack of mifepristone and misoprostol tablets. For patients at 10 weeks' gestation or more, you should provide an additional dose of misoprostol to minimise the risk of an incomplete abortion. Traditional misoprostol administration has been by the vaginal route, but sublingual route and buccal routes are as effective. The patient should be advised on how to self-administer by the preferred route.

    a. Oral administration (swallowing) of misoprostol has lower efficacy. Oral administration should only be used if the pregnancy is < 7 weeks' gestation and if vaginal, sublingual or buccal routes of administration of misoprostol are unacceptable to the patient.

b. The patient should be made aware that administration by sublingual or buccal route is associated with higher likelihood of side effects. Misoprostol tablets administered buccal or sublingually should be placed in the mouth for 30 minutes, may not dissolve fully and are associated with an unpleasant taste in the mouth.

11. The patient should be advised that the standard dosing interval between mifepristone and misoprostol is 24-48 hrs, based upon efficacy. **Misoprostol should thus normally be administered 24 to 48 hrs after mifepristone. Women who opt to administer misoprostol out with 24-48-hour period should be advised of the following:**

a. Longer dosing interval (48 hrs up to 72 hrs) - There is evidence that the time interval between mifepristone and misoprostol can be prolonged up to 72 hrs, with similar efficacy, although the likelihood of bleeding prior to misoprostol is increased. The dosing interval should not be extended beyond 72 hours, without a further dose of mifepristone.

b. Shorter dosing interval (simultaneous administration up to 24 hours) – There is evidence of a greater failure rate and a delay in onset of bleeding with dose intervals of less than 24 hours.

c. Women should be advised that if no/minimal bleeding at 4 hours after misoprostol administration (or concern that the pregnancy has not been passed) that they should self-administer the additional dose of misoprostol provided according to instructions. For women over 10 weeks' gestation, they may need to administer a third dose of misoprostol if there is still no bleeding within 4 hours of taking the second dose. If there is still no bleeding following the third dose, women should contact the clinic for advice.

12. Staff should complete AMAH paperwork, detailing patient understanding of treatment, the information that has been provided on what to expect at home (including information leaflet) and the 24-hour contact information for advice/concerns or emergency contact. Staff should also document when the patient will conduct the pregnancy test to confirm success of procedure.