

## Dear Colleague

# Abortion – Covid-19 – Approval For Mifepristone To Be Taken At Home And Other Contingency Measures

## **Purpose**

1. Abortion treatment remains an essential service so this letter provides details of some temporary measures to help minimise disruption to patient treatment at the current time. The primary purpose of this letter is to notify you that Scottish Ministers have granted approval for both stages of early medical abortion treatment to be undertaken in a patient's home in certain circumstances. This letter also clarifies, and advises on, some other areas of contingency planning in relation to the provision of abortion treatment in Scotland at this time.

## New early medical abortion at home approval

- 2. In addition to the existing approval for early medical abortion at home (EMAH), which allow misoprostol to be taken at a patient's home, Scottish Ministers have agreed to approve a patient's place of ordinary residence in Scotland as a class of place where mifepristone may also be taken where a medical practitioner or nurse decides that it is clinically appropriate and where it is not advisable for the patient to attend a clinic or hospital for their treatment due to risks associated with spread of COVID-19. This approval does not have an expiry date, but we intend that it will have effect for a limited period and so would revoke it and replace it with the terms of the previous approval (dated October 2017) at an appropriate time when it is judged that it is no longer necessary in relation to the pandemic response.
- 3. A copy of the signed approval is provided at Annex A.
- 4. The Scottish Abortion Care Providers (SACP) network has produced clinical guidance that all professionals are expected to follow when providing this treatment option to patients in this limited period. While there will still be some patients needing face to face treatment, this approval should minimise the number of patients at under 12 weeks gestation

From the Chief Medical Officer Dr Catherine Calderwood MA Cantab MBChB FRCOG FRCP (Ed) FRCP (Glasgow) FRCS(Ed) HonFFPH

31 March 2020

SGHD/CMO(2020)9

#### Addresses

For action
Territorial NHS Board Chief
Executives

For information
Directors of Public Health
Sexual Health and BBV Strategic
Leads
NHS Abortion Leads
Private Hospital Abortion Service
Managers

## **Further Enquiries**

Please contact Sam Baker sam.baker@gov.scot

Rachel Tatler rachel.tatler@gov.scot







needing to travel to a clinic. It will also enable NHS staff to carry out telemedicine consultations with patients remotely.

- 5. Therefore, I would encourage you to look to start offering consultations by telephone or video call as soon as possible for those patients for whom it is judged appropriate in line with the SACP guidance.
- 6. A copy of the SACP guidance is provided at Annex B.
- 7. This change comes into effect from today, 31 March 2020.

## Other considerations for supporting patients during the COVID-19 pandemic

8. I recognise that NHS Boards are under significant pressure and that treatment of patients with COVID-19 disease may restrict patient access to surgical abortions. However, in addition to putting in place telemedicine consultations and home delivery for abortion medication in line with the new approval, I would encourage you to consider resilience and contingency planning arrangements for abortion services.

## **Later Stage Abortions**

- 9. While this is only likely to affect small numbers of patients, we are aware of pressures on BPAS termination services due to COVID-19 and logistical difficulties being experienced for patients needing to travel due to hotels being closed and more limited public transport. In addition to this, BPAS has indicated that they do not have the isolation facilities to be able to accept any patients who have, or may have, COVID-19 symptoms or are needing to self-isolate because another household member may have the virus. While it may be feasible to allow a short delay in appointments for some of these patients, 24 weeks gestation remains the legal limit for almost all terminations that are carried out and so clearly delay is not likely to be feasible for those near that limit.
- 10. As a Board, you do have a responsibility to ensure that any patient who wants a termination and meets the one of the conditions set out in the Abortion Act 1967 can access one. In addition, the current advice on avoiding all but essential travel means it would be better for patients to be treated locally in as many cases as possible. Therefore, I would ask all Boards to make arrangements to ensure that any later stage patients (particularly those near the 24 week legal limit) who cannot travel to BPAS services for any reason are able to receive their treatment locally.

## Sign off of abortions by two medical practitioners (green forms)

- 11. The Scottish Government appreciates that sign off by two Registered Medical Practitioners (RMPs) may be more challenging for providers if a number of staff are off sick. However, this does remain a legal requirement. I have included the following to help with resilience.
- 12. Boards should consider whether certificate A forms can be signed electronically. Both RMPs need to sign the same form (either Word or pdf) so please bear this in mind. The Scottish Government will circulate electronic (Word and pdf) versions of certificate A to Boards, but please get in touch with Sam Baker or Rachel Tatler if you have not got access to these. I understand that abortion care providers across Boards are willing to provide mutual-aid with respect to reviewing and signing forms electronically if there are Boards who require additional support at any point. For sexual health staff, they should be able to do this







via the NASH system where the patient gives consent for their data to be shared with a doctor in another Board. Forms can also be completed and signed from any location so staff working from home can complete and sign if they have access to secure systems to enable them to review patient notes remotely.

13. However, as part of your contingency planning, it would be helpful if Boards could look at ensuring they have additional doctors willing and able to be called on if needed to help with providing opinions and second signatures.

## Mandatory abortion notifications (yellow forms)

14. Similarly, the Scottish Government appreciates that completing and returning the abortion notifications to my office on time is likely to be challenging. Returning these forms within 7 days remains a requirement of the Abortion (Scotland) Regulations 1991. At this time, the Scottish Government does not intend to take any action against those Boards who are unable to return them within this timeframe if this is for COVID-19 reasons. However, please ensure that yellow forms for all abortions are still completed and returned as soon as practicable as this will be critical in ensuring that we maintain complete, accurate and high quality abortion data in Scotland. If you run out of the notification forms over the next few months and my team are not in the office to post hard copies to you they will send you a pdf version so you can print off copies locally.

## Action

15. Chief Executives of NHS Boards should ensure that these changes are brought to the attention of all relevant staff, including abortion service and Fetal Medicine staff, and pharmacy staff. All Boards should consider what changes to existing procedures are required in order for this new early medical abortion at home option to be made available to women who meet the conditions set out in the approval and accompanying SACP clinical quidance.

Yours sincerely,

Dr Catherine Calderwood Chief Medical Officer







# The Abortion Act 1967 (Place for Treatment for the Termination of Pregnancy) (Approval) (Scotland) 2020

The Scottish Ministers make the following approval in exercise of the powers conferred by section 1(3) and (3A) of the Abortion Act 1967<sup>1</sup>, 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-

"coronavirus" means severe acute respiratory syndrome coronavirus 2;

"home" means the place in Scotland where a pregnant woman is ordinarily resident;

"pregnancy" and "pregnant woman" are to be construed by reference to the Abortion Act 1967; and "treatment" means the taking of the medicines known as mifepristone and misoprostol or, where the manner of treatment is that specified in paragraph 5, the taking of the medicine known as misoprostol alone.

## Approval of class of place

- 3. 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 where treatment for termination of pregnancy may be carried out where that treatment is carried out in the manner specified in either paragraph 5 or paragraph 6.
- 4. Treatment may only be carried out in the manner specified in paragraph 6 where, in circumstances where there is a serious and imminent threat to public health posed by the incidence and spread of coronavirus in Scotland, a registered medical practitioner or registered nurse acting under the direction of a registered medical practitioner considers that it is not advisable or not possible for the pregnant woman to attend a clinic.
- 5. The treatment must be carried out in the following manner-
- (a) the pregnant woman has attended a clinic 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 clinic and wants to carry out the treatment at home.
- 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 and has been prescribed mifepristone and misoprostol to be taken for the purposes of termination of her pregnancy; and
- (b) the pregnant woman wants to carry out the treatment at home.

<sup>&</sup>lt;sup>1</sup> c.87. Section 1(3A) was inserted by section 37(3) of the Human Fertilisation and Embryology Act 1990.







## Revocation

7. The Abortion Act 1967 (Place for Treatment for the Termination of Pregnancy) (Approval) (Scotland)  $2017^2$  is revoked.

Authorised to sign by the Scottish Ministers 30 March 2020

INVESTOR IN PEOPLE





<sup>&</sup>lt;sup>2</sup> Made on 26<sup>th</sup> October 2017.

## 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 selfadministration 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 <u>not</u> 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

Inherited porphyria
Chronic adrenal failure
Known or suspected ectopic
pregnancy
Uncontrolled severe asthma
Previous allergic reaction to one of
drugs involved

## Caution required in the following circumstances (discuss with senior medical staff)

Woman on long-term corticosteroids

Asthma (avoid if severe)

Haemorrhagic disorder or on anticoagulant therapy Prosthetic heart valve or history of endocarditis

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 quidelines.
- 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 buccally 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 EMAH 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.







## **Appendix**

## **Guidance on Completing Notification Forms for EMAH**

IE PREGNANCY WAS TERMINATED AT (	to be completed for all termi	nations):-	
me of hospital/approved place/other place	(address)		
	********		
	on (date)		
			_
Place of treatment" fields sho	uld <u>not</u> be left bla	ink for either Ant	iprogesterone <u>o</u>
taglandin			
er state clinical setting or if he	ome state <i>"at ho</i>	me"	
er state clinical setting or if he for the sta	ome state "at ho	me"	
If Antiprogesterone was used:-	Date of administra	Prostaglandin	
If Antiprogesterone was used:- Antiprogesterone  Date of administration	. Date of administ	Prostaglandin ration	(Mass
If Antiprogesterone was used:- Antiprogesterone	. Date of administ	Prostaglandin	(Mass
If Antiprogesterone was used:- Antiprogesterone  Date of administration  give name and address of place	Date of administ give name and address of place	Prostaglandin ration	
If Antiprogesterone was used: Antiprogesterone  Date of administration  give name and address	Date of administ	Prostaglandin ration	****
If Antiprogesterone was used:- Antiprogesterone  Date of administration  give name and address of place	Date of administ give name and address of place of treatment	Prostaglandin ration	

3) Please ensure the LMP box is ticked when gestation is estimated on patient reported dates

CURRENT PREGNANCY			
Gestation in Weeks(tick appropriate box(es))	based on	1 LMP	2 Ultrasound
The state of the s		3 Other	Specify