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Dear Colleague

## ABORTION – IMPROVEMENT TO EXISTING SERVICES – APPROVAL FOR MISOPROSTOL TO BE TAKEN AT HOME

## Purpose

1. The purpose of this letter is to notify you that Scottish Ministers have granted approval for the second stage of early medical abortion treatment to be undertaken in a patient's home in certain circumstances.

### Context

2. Following careful consideration, Scottish Ministers have agreed to approve a patient's place of ordinary residence in Scotland as a class of place where treatment for termination of pregnancy may be carried out where that treatment is carried out in accordance with following conditions;

(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.

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.

5. A copy of the guidance is provided at annex B.

# 6. This change comes into effect from tomorrow, 27 October 2017.

#### From the Chief Medical Officer Dr Catherine Calderwood MA FRCOG FRCP(Edin)

#### Enquiries to:

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Addresses For action NHS Chief Executives

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

#### **Further Enquiries**

Please contact Sarah Dillon Sarah.dillon@gov.scot



## Action

7. Chief Executives of NHS Boards should ensure that this change is brought to the attention of all relevant staff. All Boards should consider what changes to existing procedures are required in order for this option to be made available to women who meet the conditions set out in the approval and accompanying clinical guidance.

Yours sincerely

Catherine Calderwood

Dr Catherine Calderwood **Chief Medical Officer** 



## The Abortion Act 1967 (Place for Treatment for the Termination of Pregnancy) (Approval) (Scotland) 2017

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-

"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 medicine known as misoprostol.

#### 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 paragraph 4.

4. 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.

(`lA

Authorised to sign by the Scottish Ministers 26th October 2017



<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.

## Early Medical Abortion at Home up to 9 weeks + 6 Days gestation (EMAH) Guidelines for early medical abortion with self-administration of misoprostol in the home setting

## <u>Purpose</u>

The purpose of this document is to provide a guideline for the provision of take-home misoprostol for early medical abortions, where patients up to 9 weeks + 6 days gestation, can go home to self-administer misoprostol and pass the pregnancy.

## Introduction

Evidence has clearly demonstrated that early medical discharge with at home selfadministration of misoprostol is a safe method of abortion, with no higher risk of complications than medical abortions as a day case.<sup>i</sup>

This offers additional choice to women requesting an abortion and, in addition to practical and logistical benefits, enables women to complete treatment in an environment where they feel most comfortable.

Women meeting the inclusion criteria will be required to attend the clinic for mifepristone administration. They will then have the option to be discharged home to self-administer misoprostol at an agreed time interval and pass the pregnancy.

## **Inclusion Criteria**

- Certain of decision to have abortion and wishes to pass the pregnancy at home
- Fulfils the criteria set out in the Abortion Act 1967
- Is ordinarily resident in Scotland
- $\leq$  9 weeks + 6 days confirmed pregnancy on the day of mifepristone administration
- 16 years of age or above, unless considered clinically appropriate
- Can provide contact details required for follow-up
- Adult to be at home with them following the self-administration of misoprostol.
- No significant medical conditions or contraindications to medical abortion
- Does not require interpreter and is able to read competently in English
- No cause for concern regarding wellbeing at home
- 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 anticoagulant therapy
Uncontrolled severe asthma Previous allergic reaction to one of drugs involved	Prosthetic heart valve or history of endocarditis
	Pre existing heart disease
	Hepatic or renal impairment
	Severe anaemia
	Severe inflammatory bowel disease eg. Crohns
	IUCD in place (remove pre procedure)

## Day of Mifepristone administration

- 1. Confirm that patient is certain of decision to proceed with abortion, including the selfadministration of misoprostol at home.
- 2. Check that patient will have an adult at home with them after they self-administer misoprostol.

If there is no adult available to be at home with the patient then treatment as <u>EMAH should not proceed.</u> Patient may be admitted and treated as a day case that day (if space available) or offered another date for day case treatment or for EMAH (if criteria for EMAH can be fulfilled on the new date).

3. Discuss contraception options and provide on-going contraception in line with national guidelines<sup>ii</sup>

N.B. for women choosing EMAH who wish an implant, this should be inserted prior to discharge home. Local pathways for insertion post procedure should be in place

4. Check full blood count result.

If Hb< 10 g/dl then seek medical advice about need for treatment of anaemia (oral vs. systemic haematinics or blood transfusion) and ward admission for misoprostol treatment. Blood tests for investigation of cause of anaemia should also be taken



before haematinics commenced. A decision to delay medical abortion needs to be balanced against the risk of increased blood loss with higher gestations.

- 5. Undertake STI screening and follow up in line with local policy.
- 6. Administer 200 mg mifepristone orally. If vomiting occurs within 2 hours then treatment with mifepristone needs to be repeated (Consider if patient requires admission for day case instead of EMAH)
- 7. Check blood group and administer Anti D if necessary. If blood group not known advise women in line with local protocol and national guidelines.
- 8. Dispense take-home pack of prescribed analgesia.
- 9. Dispense take-home pack of misoprostol tablets. Traditional administration has been by the vaginal route, but sublingual route and buccal routes are as effective and the patient should be advised on how to self-administer by the preferred route.
  - a. If vaginal administration is unacceptable to the patient, then the same dose of misoprostol may be administered sublingually or buccally with similar efficacy. Please note oral administration (swallowing) of misoprostol has lower efficacy and so 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 headache. Misoprostol tablets administered buccally or sublingually may take approximately 20 minutes to dissolve, may not dissolve fully and are associated with an unpleasant taste in the mouth.
- 10. The patient should be advised of the standard dosing interval between mifepristone and misoprostol is 24-48 hrs, based upon efficacy. **Misoprostol should thus normally be administered** <u>24 to 48 hrs after mifepristone.</u>
  - a. Longer dosing interval (> 48 hrs 72 hrs) There is evidence that (< 63 days gestation) the time interval between mifepristone and misoprostol can be prolonged up to 72 hrs after mifepristone, with similar efficacy, although the likelihood of heavy bleeding by this time is increased.
  - b. Longer dosing intervals (> 48-72 hrs) should only be used if the patient is aware of the likelihood of heavy bleeding with treatment in this way, and the standard (24-48 hrs) dosing interval is not acceptable to the patient.
- 11. Complete EMAH paperwork<sup>iii</sup>, detailing patient understanding of treatment and provide patient information leaflet with advice on what to expect at home.



Please ensure when completing the Notification of Abortion form that you record the location of the place of treatment. The section on prostaglandins administration should record the patients address. It is sufficient to record the address as 'place of residence' or 'home' as this must be recorded on the first page of the form. Type of premises should be recorded as home. 'Date of administration of prostaglandins' should be recorded as the date on which you advise the patient selfadministers misoprostol. <u>Guidance for completing the Notification of</u> <u>Abortion form</u>.

- 12. Ensure that a plan for follow-up has been made (telephone follow- up, selfassessment or clinic follow- up). Please ensure patient understands how to perform the pregnancy test according to instructions if required as part of follow up plan. If telephone follow-up is chosen, ensure patient provides a reliable contact number and agree a date and time for telephone follow-up.
- 13. Advise patient on signs and symptoms that should warrant re-attendance to hospital as an emergency.
- 14. Advise patient that they should contact the clinic if they have any of the following as the procedure may not have been effective:
  - If they do not bleed within 24 hours of receiving misoprostol tablets
  - If they have less than 4 days of bleeding
  - If they still 'feel' pregnant at the end of one week or have symptoms of pregnancy such as sore breasts, sickness, tummy growing etc.
  - If the low sensitivity pregnancy test is positive or 'invalid'
  - If the next period does not come one month after treatment
  - If they remain concerned that they may still be pregnant
  - If they fail to take the misoprostol as instructed
- 15. Advise those patients breastfeeding that milk should be discarded for 6 hours after misoprostol administration.
- 16. Ensure the patient has been provided with:
  - Complete drug regime
  - Emergency contact information
  - Contact information for routine advice and queries
  - Advice about how to self-administer misoprostol
  - EMAH information leaflet
  - Contraception of their choice
  - Pregnancy test
  - Advice about how to administer a pregnancy test
  - Copy of discharge letter
- 17. Discharge patient and ensure an appropriate discharge letter has been completed (either a TRAK (or similar) letter or a 'To whom it may concern' letter).



In the case of an invalid or lost pregnancy test, women should be seen as soon as possible at the local abortion service or via the most appropriate local pathway.

If an on-going pregnancy is confirmed then the woman should be offered the next available date for abortion by the most appropriate method for her gestation.

If the patient does not complete their follow up plan local protocols for patient follow up should be used.

- https://www.fsrh.org/news/new-fsrh-guideline--contraception-after-pregnancy/
- <sup>III</sup> Guidance for completing the Notification of Abortion form



<sup>&</sup>lt;sup>i</sup> <u>http://www.medscape.com/viewarticle/755739</u> Comparison of Unscheduled Re-attendance and Contraception at Discharge, Among Women Having the Final Stage of Early Medical Abortion at Home and Those Remaining in Hospital - Hannah Astle, Sharon T Cameron, Anne Johnstone