WHC/2018/027

WELSH HEALTH CIRCULAR

Llywodraeth Cymru
Welsh Government

Issue Date: 29 June 2018

STATUS: ACTION

CATEGORY: LEGISLATION/DELIVERY

Title: Early Medical Abortion - second medication (Misoprostol) in a medical termination, to be self-administered at home

Date of Expiry / Review N/A

For Action by:
Chief Executives of health boards

Action required by:

Sender: Professor Chris Jones, Deputy Chief Medical Officer, Deputy Director Population Healthcare Division, Welsh Government.

HSSG Welsh Government Contact(s) :
Richard Chivers, Women and Children Health Branch, Population Healthcare. Cathays Park, Cardiff CF10 3NQ Tel:03000 251534

Enclosure(s): Ministerial approval, guidance

Dear Colleague,

TERMINATION OF PREGNANCY - APPROVAL FOR MISOPROSTOL TO BE TAKEN AT HOME

1. The purpose of this Welsh Health Circular is to inform you that Welsh Ministers have granted approval for the second stage of early medical termination of pregnancy to be undertaken in the patient's home.

2. Welsh Ministers have agreed to approve a patient's place of ordinary residence in Wales 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 wishes to carry out the second treatment at home.

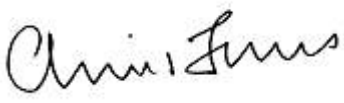
3. A copy of the signed approval is provided at annex A and a copy of the clinical guidance is at annex B.

4. Chief Executives of NHS Boards must ensure that this change is brought to the attention of all relevant staff.

5. I require assurance from Chief Executives that relevant changes to existing procedures will be made to ensure this option is made available to women who meet the conditions set out in the approval and accompanying clinical guidance. I should be grateful if you would confirm your plans for implementation at the following address by 31 July 2018.

   Email: WomensHealth@gov.wales

Yours sincerely



PROFESSOR CHRIS JONES

Deputy Chief Medical Officer
Deputy Director Population Healthcare Division
Welsh Government

The Abortion Act 1967 (Approval of Place for Treatment for the Termination of Pregnancy) (Wales) 2018

Made *20th June 2018-* ***

The Welsh Ministers give the following approval in exercise of the powers conferred on the Secretary of State by section 1(3) and (3A) of the Abortion Act 1967(**1**) and now vested in them.

Commencement

1. This approval comes into force on the date it is made.

Interpretation

2. In this approval—

"home" ("*cartref*") means the place in Wales where a pregnant woman is ordinarily resident;

"pregnancy" ("*beichiogrwydd*") and "pregnant woman" ("*menyw feichiog*") are to be construed by reference to the Abortion Act 1967; and

"treatment" ("*triniaeth*") 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 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 the termination of pregnancy; and

(b) the pregnant woman has taken mifepristone at that clinic and wants to carry out the treatment at home.

Signed by Vaughan Gething
Cabinet Secretary for Health and Social Services, one of the Welsh Ministers
Date:

(**1**) 1967 c.67. Section 1(3A) was inserted by section 37(3) of the Human Fertilisation and Embryology Act 1990. The powers of the Secretary of State were transferred, in relation to Wales, to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672). The functions of the National Assembly for Wales were transferred to the Welsh Ministers under section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006 (c.32).

Early Medical Abortion at Home up to 9 weeks + 6 Days gestation (EMAH)

Guideline for early medical abortion with self-administration of misoprostol in the home setting

Purpose

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 self-administration of misoprostol at home is a safe method of abortion, with no higher risk of complications than medical abortions as a day case[i].
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 a clinic in Wales 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. All abortifacient medicines will be dispensed by the clinic.

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 Wales
- Gestational age of ≤ 9 weeks + 6 days on the day of mifepristone administration
- Is able to communicate satisfactorily with clinical staff
- Can provide contact details required for follow-up
- Safeguarding and social circumstances are satisfactory
- An adult should usually be at home following the self-administration of misoprostol except in special circumstances and after review by a senior clinician
- No significant medical conditions or contraindications to medical abortion
- No cause for concern regarding wellbeing at home
- 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 Chronic adrenal failure Known or suspected ectopic pregnancy Uncontrolled severe asthma Previous allergic reaction to one of drugs involved	Woman on long-term corticosteroids Asthma (avoid if severe) Haemorrhagic disorder or anticoagulant therapy 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 self-administration 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 EMAH should not proceed. 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 [ii]

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. Consider full blood count when clinically indicated (recent pregnancy, h/o anaemia etc.)

   If Hb is subsequently found to be < 10 g/dl seek medical advice about need for treatment of anaemia (oral vs. systemic haematinics or blood transfusion) and arrange ward admission for misoprostol treatment.

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.

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 24 to 48 hrs after mifepristone.**

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 [iii], 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 self-administers misoprostol.**
***(Insert link to** Guidance for completing the Notification of Abortion form.)*

12. Ensure that a plan for follow-up has been made (telephone follow- up, self-assessment or clinic follow- up). Please ensure patient understands how to perform a urine pregnancy test. 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 the transfer of medicines into breastmilk is minimal and not thought to be harmful. 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
- Copy of discharge letter

17. Discharge patient and ensure an appropriate discharge letter has been completed

- **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.**

[i] [i] http://www.medscape.com/viewarticle/755739 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

[ii] [ii] https://www.fsrh.org/news/new-fsrh-guideline--contraception-after-pregnancy/

[iii] Reference to Welsh Government document for legal framework