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Lancashire and South Cumbria
Integrated Care Board

Update for Primary Care: Topiramate (Topamax): New Pregnancy Prevention Programme

Document Control

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Change Control		
This section outlines changes from version X.X to version X.X of this guidance		
Summary and description of change		Date
1.		
2.		
3.		

Background

Following the June 2024 Drug Safety Update, topiramate is now:

- Contraindicated (should not be used) in pregnancy.
- Contraindicated in women of childbearing potential unless the conditions of a Pregnancy Prevention Programme (PPP) are fulfilled.

These conditions are also applicable to female patients who are not sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

The use of topiramate during pregnancy is associated with significant harm to the unborn child, included a higher risk of congenital malformation, low birth weight and a potential increased risk of intellectual disability, autistic spectrum disorder and attention deficit hyperactivity disorder in children of mothers taking topiramate during pregnancy.

The PPP aims to ensure that women of childbearing potential:

- Are informed of the risks of topiramate (a Patient Guide for Epilepsy or Migraine Prophylaxis is available).
- Are using highly effective contraception (HEC) throughout treatment and for at least **four weeks** after the last dose of topiramate (topiramate is an enzyme inducer that reduces effectiveness of hormonal contraceptives and there are limited options for HEC see FSRH CEU Guidance | FSRH point 9 and see aide-memoire_table-2024.pdf (publishing.service.gov.uk)).
- Have an **Annual** Risk Awareness Form (ARAF) completed during a consultation with a *healthcare professional* to document discussion of the risks (there are separate forms for Epilepsy and Migraine Prophylaxis). This must be done at treatment initiation *and* annually thereafter.

A Healthcare Professional's Guide to the PPP is available for Epilepsy and Migraine Prophylaxis.

Advice to healthcare professionals in primary care

1. Identify all women and girls of childbearing potential (10 years – 55years) on topiramate using EMIS search (searches to identify women and girls prescribed topiramate who may require the PPP can be requested for from your local medicines optimisation team, or, if a practice has Ardens – Ardens resources should be used).
2. Ensure there is a correct read coded indication for topiramate (SNOMED code linked to the drug) within the clinical record. This will be epilepsy or migraine prophylaxis in most cases.
3. Identify any women who are currently pregnant and prescribed topiramate. Topiramate is contraindicated in pregnancy for prophylaxis of migraine and should be stopped straight away. *Topiramate for epilepsy should not be stopped abruptly or without specialist input* - work with local specialist/neurology teams.
4. For women of childbearing potential who are not pregnant:
    a. Bring the patient in for a review as soon as possible to discuss the need for them to be on the PPP. Whilst awaiting appointment, and to enable quick access to the information, practices should consider communication with patients via text and/or letter highlighting the risks with topiramate and need to be on PPP.
    b. Assess the patient's potential for pregnancy.
    c. Identify, and prioritise for documented discussion, those of childbearing potential who are not using HEC. Please see FSRH CEU Guidance point 9 and aide-memoire_table-2024.pdf (publishing.service.gov.uk).
    d. During the review inform the patient of the potential risks of topiramate in pregnancy.

With acknowledgement to Bath and North East Somerset, Swindon and Wiltshire ICB (Memo-for-Primary-Care-Introduction-of-Topiramate-Pregnancy-Prevention-Programme-v-2.0-July-24.pdf (bswtogether.org.uk))
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e. Discuss with the patient the need to use highly effective contraception (IUS/IUD) throughout treatment and for at least four weeks after the last dose of topiramate. Please see FSRH CEU Guidance point 9 and aide-memoire_table-2024.pdf (publishing.service.gov.uk). Commence HEC where appropriate.
f. If a decision is made not to use HEC: Establish if the decision not to use HEC is an informed choice or an oversight? HEC is the optimal choice. Any decision by the patient not to use HEC should be an informed choice and discussions should be documented in the patient's clinical notes.
g. Provide those of childbearing potential with the appropriate Patient Guide Epilepsy or Migraine Prophylaxis for the PPP.
h. *Advise patients prescribed topiramate for epilepsy not to stop taking topiramate without the advice of a specialist as this will risk worsening epilepsy*.
i. Advise women with a history of migraine to stop topiramate should they discover that they are pregnant.
j. Complete the ARAF with the patient (or responsible person) and save the ARAF in the clinical record. Add the relevant read code depending on clinical indication (see flow charts below).
k. Where applicable, ensure a patient recall mechanism is in place so the patient can be called back into the practice after 12 months for their annual review.
l. **If a decision is made to refuse to participate in the PPP**, ensure the decision is an informed choice and discussions documented, and add the relevant read code in the clinical record - "Pregnancy Prevention Programme declined" (SNOMED Code: 1129801000000100).

5. If you, as the healthcare professional, consider there is a compelling reason that there is no potential for pregnancy add the topiramate PPP is not needed read code, see flow charts below.

With acknowledgement to Bath and North East Somerset, Swindon and Wiltshire ICB (Memo-for-Primary-Care-Introduction-of-Topiramate-Pregnancy-Prevention-Programme-v-2.0-July-24.pdf (bswtogether.org.uk))
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Flow Chart A: Indication - prophylaxis of migraine

Female patient of childbearing potential (10 years – 55 years) on topiramate.

Patient pregnant

If currently pregnant and prescribed topiramate:
- Topiramate is contraindicated in pregnancy for prophylaxis of migraine and should be stopped straight away and alternative treatment discussed.

Patient NOT pregnant

Confirm indication – migraine prophylaxis and ensure correctly read coded on clinical system.

Review migraine prophylaxis choice (is it still required?) and inform patient of the risk of taking topiramate by using Patient Guide Migraine

Is there a compelling reason that indicates there is no potential for pregnancy e.g. hysterectomy?

Yes

Is potential for pregnancy status possible to change in the future?

No

Total hysterectomy

- Complete ARAF Step 1 with the patient and code "Topiramate PPP ARAF for Prophylaxis of Migraine" (2181261000000109)
- Document the compelling reason that indicates no potential for pregnancy
- Code "PPP not needed" (1129791000000104)
- Code "Total hysterectomy" (116140006)

Yes

Consider if topiramate is still indicated/the best option or if a switch to an alternative medication is possible.

If topiramate considered the only suitable treatment option:
- Complete ARAF Step 1 with the patient and add code "Topiramate PPP ARAF for Prophylaxis of Migraine" (2181261000000109)
- Document the compelling reason that indicates no potential for pregnancy
- Code "PPP not needed" (1129791000000104)
- Ensure a patient recall mechanism in place to allow call back after 12 months.

No

Does patient wish to continue with topiramate for migraine prophylaxis?

No

Consider if topiramate is still indicated/the best option.

Adults: Consider switching to an alternative using LSCMMG headache management pathway. Clinical Guidelines - Lancashire and South Cumbria Medicines Management Group (lancsmmg.nhs.uk)
If the patient has tried the other options from the pathway, but these have been unsuccessful then seek advice from specialist.

Paediatrics: seek advice from specialist before making any changes to medication.

Yes

Obtain informed consent to continue with prophylaxis.

*Pregnancy Prevention Programme (PPP) Applicable**
- Complete ARAF Step 1&2 with the patient and add read code "Topiramate PPP ARAF for prophylaxis of migraine" (2181261000000109)
- Code "PPP started" (1129771000000103)
- Organise annual review.
- Ensure patient recall mechanism in place to allow call back after 12 months.

*For women and girls of childbearing potential who remain on topiramate and PPP is applicable: Discuss with patient(s) the need to use highly effective contraception (HEC) (IUS/IUD) throughout treatment and for at least four weeks after the last dose of topiramate. Commence HEC where appropriate.

Specific actions for those with an indication of migraine prophylaxis:

- Do NOT routinely refer women of childbearing potential prescribed topiramate for migraine prophylaxis to the neurology/specialist teams.
- Only seek advice from neurology if alternative treatment options unclear or clinical complexity.
- If patient currently under follow up with the specialist/neurology team e.g. paediatric patients – seek advice from the relevant specialist/neurology team before making any changes to medication.
- For women and girls of childbearing potential who remain on topiramate for migraine prophylaxis who are not managed by neurology, a primary care healthcare professional should ensure the requirements of the PPP are in place and complete the ARAF with the patient to document the discussion about risks, ensuring the ARAF is saved within the patient's clinical records and appropriate read codes recorded. You may wish to complete the ARAF at the next medication review if you are assured that the patient has been informed of the risks and appropriate highly effective contraception is currently prescribed. Agree as a practice which healthcare professional within the practice is most appropriate to undertake this task.
- Ensure completed ARAF forms are uploaded into patient clinical notes and a copy given to the patient or representative.

With acknowledgement to Bath and North East Somerset, Swindon and Wiltshire ICB (Memo-for-Primary-Care-Introduction-of-Topiramate-Pregnancy-Prevention-Programme-v-2.0-July-24.pdf (bswtogether.org.uk))
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Flow Chart B: Indication - epilepsy

Female patient of childbearing potential (10 years – 55 years) on topiramate.

Patient pregnant

If currently pregnant and prescribed topiramate:
- Topiramate for epilepsy should not be stopped abruptly or without specialist input.
- Seek urgent advice from neurology.
- Advise patient: *do not stop taking topiramate as this will risk worsening epilepsy*.

Patient NOT pregnant

Confirm indication – epilepsy and ensure correctly read coded on clinical system.

Inform patients of the risks of topiramate using Patient Guide Epilepsy and provide patients with a copy of the guide.

Is there a compelling reason that indicates there is no potential for pregnancy e.g. hysterectomy?

Yes

Is potential for pregnancy status possible to change in the future?

No

Total hysterectomy

- Complete ARAF Step 1 with patient and code "Topiramate PPP ARAF for Epilepsy" (2181251000000106)
- Document the compelling reason that indicates no potential for pregnancy
- Code "PPP not needed" (1129791000000104)
- Code "Total hysterectomy" (116140006)

Yes

- Complete ARAF Step 1 with patient and code "Topiramate PPP ARAF for Epilepsy" (2181251000000106)
- Document the compelling reason that indicates no potential for pregnancy
- Code "PPP not needed" (1129791000000104)
- Confirm patient remains under neurology specialist and has a follow up/review date within the next 12 months.
- Ensure patient recall mechanism in place to allow call back after 12 months.

No

Does patient wish to change their medication as a result of the discussion of the risks/alert?

Yes

Refer patient back to neurology.
To ensure continuity of care: ensure referrals include patient's named neurology consultant.
If patient has been discharged/not known to neurology specialist: Initiate new referral and highlight "Topiramate Pregnancy Prevention Programme" as referral reason.
Remind the patient: Do not stop taking topiramate as this will risk worsening epilepsy. Do not to stop contraception without the advice of the specialist.

No

Obtain informed consent to continue with topiramate.

*Pregnancy Prevention Programme (PPP) Applicable**
- Complete ARAF Step 1&2 with patient and code "Topiramate PPP ARAF for Epilepsy" (2181251000000106)
- Code "PPP started" (1129771000000103)
- Confirm patient remains under neurology specialist and has a follow up/review date within the next 12 months.
- Send a copy of ARAF to the patient's secondary care neurology consultant for specialist signature. Specialist to sign form and return form to GP practice to upload and record into the patient's clinical notes.
- Organise annual review.
- Ensure patient recall mechanism in place to allow call back after 12 months.

*For women and girls of childbearing potential who remain on topiramate and PPP is applicable: Discuss with patient(s) the need to use highly effective contraception (HEC) (IUS/IUD) throughout treatment and for at least four weeks after the last dose of topiramate. Commence HEC where appropriate.

Specific actions for those with an indication of epilepsy:

- Advise patients: *Do not stop taking topiramate without the advice of a specialist as this will risk worsening epilepsy*.
- Patients who have been discharged from neurology services and/or are not known to neurology services should be referred back into the service: initiate a new referral and highlight "Topiramate Pregnancy Prevention Programme" as referral reason.
- Patients who wish to become pregnant or wish to change their medication because of the alert should be referred back to their neurology consultant and highlight "Topiramate Pregnancy Prevention Programme" as referral reason.
- Where pregnancy prevention programme is not applicable and pregnancy status unlikely to change in the future e.g. total hysterectomy, a referral back to neurology is not required.
- Those patients who are still under the care of neurology for epilepsy but without clear next follow up or review date: liaise with consultant to ensure patient will be seen within the next 12 months.
- The DVLA have indicated that if a person is changed to a less effective anti-seizure medication in epilepsy, then 6 months of not driving is required.
- Ensure completed ARAF forms are uploaded into patient clinical notes and a copy given to the patient or representative.

With acknowledgement to Bath and North East Somerset, Swindon and Wiltshire ICB (Memo-for-Primary-Care-Introduction-of-Topiramate-Pregnancy-Prevention-Programme-v-2.0-July-24.pdf (bswtogether.org.uk))
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Flow Chart C: Indication not epilepsy or migraine prophylaxis

Female patient of childbearing potential (10 years – 55 years) on topiramate.

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Ascertain indication – e.g. idiopathic intracranial hypertension and ensure correctly read coded on clinical system.

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- **Off-label or unlicensed indication:**
  - Review indication and seek advice from relevant specialist team e.g. Pain Clinic, Mental Health Team.
  - Referral back to initiating specialist to complete ARAF.
  - Whilst awaiting referral discuss the PPP and address any questions.
  - If PPP not applicable code “PPP not needed” (1129791000000104)
  - If PPP applicable code “PPP started” (1129771000000103)
  - Ensure patient is provided with information around risks of topiramate and information around HEC. Commence HEC where appropriate.
  - Once completed AFAF form/letter received from specialist code “Topiramate PPP ARAF completed” (2181271000000102)

With acknowledgement to Bath and North East Somerset, Swindon and Wiltshire ICB (Memo-for-Primary-Care-Introduction-of-Topiramate-Pregnancy-Prevention-Programme-v-2.0-July-24.pdf (bswtogether.org.uk))

Appendix 1: MHRA Aide-Memoire Table

Medicines & Healthcare products Regulatory Agency

Pregnancy testing and contraception for pregnancy prevention during treatment with medicines of teratogenic potential

- **Risk of pregnancy should be assessed prior to each teratogen prescription**
  - Risk of pregnancy may be high at start of a method or when switching between methods due to risk of pregnancy from unprotected sex prior to starting the method, unreliable use of the previous contraceptive method, and/or time needed to establish contraceptive efficacy at the start of the new method.
  - Pregnancy tests at start of contraceptive method may not detect an early pregnancy following unprotected sex in the last 3 weeks
- **Any starter on new method contraception should have a repeat pregnancy test at 3 weeks if there is any risk of pregnancy at start of contraceptive method**
- The duration of teratogen prescriptions may need to be shortened for patients who use contraceptive methods that require frequent pregnancy testing

Effectiveness of contraceptive in typical use[1]	Contraceptive method	Duration contraceptive method used / other situations	Pregnancy test needed before next teratogen prescription?
Highly effective methods **(Typical use failure rates less than 1%)**	Copper intrauterine device (copper IUD)	Established user more than 3 weeks to 5 to 10 years (depending on IUD[2])	No
	Levonorgestrel-releasing intrauterine system (LNG-IUS)	Established user more than 3 weeks to 3 to 8 years (depending on IUS[2])	No
	Progestogen Implant	Established user more than 3 weeks to 3 years	No
		Established user (more than 3 weeks), but concurrent use of interacting medicines which may affect efficacy[3]	Yes + review / refer for contraceptive advice
Effective methods **(Typical use failure rates greater than 1%)** **Additional barrier methods are advised during teratogen use**	Depot medroxyprogesterone acetate (DMPA) subcutaneous (SC) or intramuscular (IM) injections[4]	Established user (more than 3 weeks + repeat injections on schedule) and less than 13 weeks since last injection + documented as administered by healthcare professionals	No
		Established user (more than 3 weeks + repeat injections on schedule and less than 13 weeks since last injection) but self-administered or undocumented administration	Yes, test if any suspected risk of pregnancy
		More than 13 weeks since last injection (ie, beyond recommended duration of use of last injection)	Yes + review / refer for contraceptive advice
	Combined hormonal contraceptives (pills, patches or vaginal ring) or progestogen-only pills	Established user (more than 3 weeks), reliable and consistent use	Yes, test if any suspected risk of pregnancy
		Established user (more than 3 weeks) but with unreliable or inconsistent use of method, eg, • missed pills, late patch • diarrhoea or vomiting • use of other interacting medicines that may affect efficacy[3]	Yes + review / refer for contraceptive advice
	Other methods or no contraception	Any duration of use of other methods	Yes + review / refer for contraceptive advice;
		No contraception	Assess need for contraception + test if any suspected risk of pregnancy + review / refer for contraceptive advice

Explanatory notes:

1. Effectiveness of methods are based on failure rates in typical use (which includes risk of user error) rather than perfect use. Perfect use failure rates are similar for specific methods listed (0.03–0.6%) but risk of user error is higher for daily methods than for long-acting reversible contraceptive (LARC) methods and are highest for methods used at time of sexual intercourse. Highly effective methods are based on less than 1% failure rate in typical use; Less effective methods are based on greater than 1% failure rate (6–9%) in typical use (Trussell J. Contraception. 2011; 83: pages 397 to 404).
2. Refer to Product Information for specific products; patients should be reviewed / referred for contraception advice at the end of the recommended duration of use.
3. Implants are only considered as highly effective and combined hormonal contraceptives and progesterone-only pills are only considered as effective if interactions with any concurrent medicine are not a concern (see FSRH guidance on drug interactions with hormonal contraception [2022]).
4. DMPA (IM or SC) injection can be considered as highly effective if it is administered by healthcare professionals and continuous repeat use is documented as occurring within recommended duration of action (equivalent to perfect use, failure rate = 0.2%). Otherwise it is considered an effective contraceptive (typical use failure rate = 6%). The same rationale should be used for other injection products with different recommended duration of action (eg, norethisterone enanthate).

Example Scenarios: Topiramate new safety measures

Patient scenario	What can I do to support the MHRA safety recommendations for topiramate?
A female **adult epilepsy** patient of childbearing age prescribed topiramate. Topiramate being prescribed by primary care.	Follow flow chart B
A female **adult** patient of childbearing age taking topiramate for **migraine**, prescribed by primary care.	Primary care should in the first instance review the patient's topiramate medication and assess if it is still required? **If no longer required:** Consider stopping topiramate medication as appropriate. If on contraception, ensure the contraception is continued for 4 weeks after stopping treatment due to topiramate being an enzyme inducing drug. **If still required:** • Follow flow chart A *Remember the use of topiramate is now contraindicated in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled. If prescribers choose to continue the prescribing of topiramate in a female of childbearing age without prescribing contraception/engagement with the PPP the prescriber is accountable and should make records of the steps they have taken to manage the risk, the conversation with the patient and include any referrals that have been made. The waiting time for a non-urgent neurology appointment will need to be considered. The decision to prescribe will need to be on a case-by-case basis considering individual patient circumstances. Prescribers should consider the good practice guidance from the GMC guidance or GPhC.*
A female **paediatric patient** (<18 years) taking topiramate for **migraine**, prescribed by primary care.	• Follow flow chart A. • Topiramate is unlicensed for use in children for migraine prophylaxis and the patient should be under follow up with the specialist / neurology team. • Seek advice from the relevant specialist / neurology team before making any changes to medication. • Where the child is post menarche ensure they are following the Pregnancy Prevention Programme (PPP).
A female patient of childbearing age prescribed topiramate for a **non-licensed / non-formulary indication** e.g. tics for Tourette's syndrome, idiopathic intracranial	Prescribing for these indications is currently outside of the LSCMMG formulary. Follow flow chart C. GP practices should refer patients to the appropriate secondary care team/specialist for review of treatment, completion of ARAF and ongoing monitoring. GP practices should discuss the risks of topiramate with the patient and ensure they are following the Pregnancy Prevention Programme (PPP).

With acknowledgement to Bath and North East Somerset, Swindon and Wiltshire ICB (Memo-for-Primary-Care-Introduction-of-Topiramate-Pregnancy-Prevention-Programme-v-2.0-July-24.pdf (bswtogether.org.uk))
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hypertension or prescribing in pain.	
Patient on topiramate for **epilepsy** and wants to start a family or are pregnant.	• If pregnant, the patient should be highlighted to the neurology team in secondary care urgently and advice sought. • If patient wanting to start a family, but is not currently pregnant, the patient should be referred back to neurology for review with consultant/specialist. • Topiramate for epilepsy should **not be stopped abruptly** or without specialist input. • Advise the patient: Do not stop taking topiramate **without the advice of a specialist as this will risk worsening epilepsy.** • **If patient on contraception -** Ask the patient not to stop contraception without the advice of the specialist.
Patient on topiramate for **migraine** and wants to start a family or are pregnant.	• Discontinue topiramate in individuals who are pregnant. Topiramate is now contraindicated in pregnancy for prophylaxis of migraine. • Discontinue topiramate in individuals who are planning a pregnancy. Migraine often improves in pregnancy, typically during the second and third trimesters. Therefore, these individuals do not usually need preventative treatment during pregnancy. If needed, consider alternative prophylaxis medication. • The conditions of the PPP continue to apply until the topiramate has been discontinued. • Ask the patient not to stop contraception until they have no longer been taking topiramate for at least four weeks. • Patients with migraine presenting with an unplanned pregnancy should have their treatment discontinued and practices should liaise with maternity services as needed.

With acknowledgement to Bath and North East Somerset, Swindon and Wiltshire ICB (Memo-for-Primary-Care-Introduction-of-Topiramate-Pregnancy-Prevention-Programme-v-2.0-July-24.pdf (bswtogether.org.uk))

Frequently Asked Questions

1. **What contraception is recommended for those prescribed topiramate as part of the PPP?**

   The FSRH recommends at least **one highly effective** method of contraception (copper intrauterine device (Cu-IUD) or levonorgestrel intrauterine system (LNG-IUD) **OR** Depot Provera IM (DMPA) **PLUS** condoms.

   Please note: As topiramate is a teratogen, the FSRH CEU suggests that it is preferable to err on the side of caution and consider topiramate a potential enzyme inducer, regardless of dose. Therefore, the implant, combined hormonal contraception and progestogen-only pills are not deemed an appropriate option for contraception with topiramate.

   Individuals using an enzyme-inducing drug who require emergency contraception should be advised that effectiveness of oral emergency contraception could be reduced. They should be offered a copper IUD if indicated. If a copper IUD is unacceptable, unsuitable or unavailable, a double dose (3mg) of levonorgestrel oral emergency contraception or a single dose (30mg) of ulipristal acetate oral emergency contraception can be offered if indicated, with advice that effectiveness is unknown (FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) | FSRH).

   Involve the patient in the discussion about the most appropriate contraceptive method to ensure patient engagement.

   Ensure that the patient understands that even if they have amenorrhoea, they must follow all the advice on highly effective contraception.

   Consider the possibility of decreased contraceptive efficacy and increased breakthrough bleeding in patients taking systemic hormonal contraceptive products with topiramate.

   Ask patients to report any change in their bleeding patterns; contraceptive efficacy can be decreased even in the absence of breakthrough bleeding.

2. **Can GP practices start a female patient on topiramate for epilepsy?**

   No.

   All new initiations of topiramate for epilepsy must be started by specialists only. An Annual Risk Awareness Form (ARAF) will need to be completed by the specialist to support and record the discussion of risks of starting treatment with topiramate with the patient (or their responsible person or parents/care givers (if applicable)).

   Once completed, a copy of the ARAF will be given to the patient/responsible person. GP practices should also be sent a copy of the completed ARAF form from the specialists or from the patient/responsible person.

With acknowledgement to Bath and North East Somerset, Swindon and Wiltshire ICB (Memo-for-Primary-Care-Introduction-of-Topiramate-Pregnancy-Prevention-Programme-v-2.0-July-24.pdf (bswtogether.org.uk))
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The completed ARAF must be uploaded and recorded into the patient's clinical notes and the date the form was completed should be documented.

GP practices should use the following SNOMED code to code the completed ARAF form: Topiramate PPP ARAF for Epilepsy" (2181251000000106).

3. **Can GPs continue to prescribe topiramate for epilepsy once it has been initiated by a specialist and a completed ARAF form has been received?**

   Yes. But it the responsibility of the GP practice to ensure patients have a completed ARAF prior to prescribing topiramate. If an ARAF has not been completed by the specialist, patients should be referred back to secondary care immediately.

   Following initiation of topiramate by the specialist the patient will be referred back to their GP practice for ongoing prescribing. GP practices should ensure patients are offered annual medication reviews and the risks of topiramate shared/discussed with patients at each review (see flow chart B).

4. **Can GP practices start an adult female patient on topiramate for migraine?**

   Yes. But for all new women of childbearing potential prescribers must:

   - Assess their potential for pregnancy and discuss the need for them to be on the Pregnancy Prevention Programme.
   - Ensure that pregnancy has been excluded, by means of a negative pregnancy test, prior to starting treatment with topiramate and prior to issuing the first prescription.
   - Inform them of the potential risks of topiramate use in pregnancy and counsel them on treatment options, and ensure they understand the:
     - other therapeutic options available
     - risks to the unborn child if topiramate is taken during pregnancy
     - the need to take highly effective contraception throughout treatment and undergo pregnancy testing when required – e.g. if there is any reason to suggest lack of compliance or effectiveness of contraception.
     - the need to contact her primary care team urgently if they suspect they might be pregnant or wish to plan a pregnancy.
   - Discuss with them the need to use highly effective contraception (HEC) (IUS/IUD) throughout treatment and for at least four weeks after the last dose of topiramate. Arrangements should be made for HEC prior to the first prescription for topiramate being issued. See guidance from Faculty of Family Planning and Sexual Health on

potential drug interactions with hormonal contraceptives and what this means for topiramate.

- Complete the Risk Awareness Form with the patient (or responsible person). This form will need to be completed at treatment initiation *and* annually thereafter. The patient should be given a copy of the completed form.
- Provide a copy of the Patient Guide to the patient (or responsible person).
- See the patient promptly in case of unplanned pregnancy or if she wants to plan a pregnancy.

All patients on the Pregnancy Prevention Programme should be invited for an annual review and only continue if its conditions are fulfilled. Patients should have an up to date and signed annual risk awareness form. Women should be using at least one highly effective method of contraception,

5. Is there a digital version of the Risk Awareness Form (and does the from need a wet signature)?

There are electronic versions of the materials available on the electronic medicines compendium (EMC) website (medicines.org.uk). These include editable pdf versions on the Risk Awareness Forms. A wet signature is not required from either the patient or the healthcare professional, as an electronic signature is considered acceptable.