

Update for primary care: topiramate (Topamax): new pregnancy prevention programme

Date approved: 08 January 2025

Document control

Title of document: Update for primary care: topiramate (Topamax): new pregnancy prevention programme

Lead team: Medicines management team

Document type: Guidelines

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Date ratified: 08 January 2025

Ratified by: Cornwall area prescribing committee

Review frequency: 3 years

To be reviewed by date: 08 January 2028

Version control

Version number	Revision date	Revision by	Nature of revisions
V1.0			

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

Unless the conditions of the new Pregnancy Prevention Programme (PPP) are fulfilled, topiramate is now contraindicated in women of childbearing potential. The use of topiramate during pregnancy is associated with significant harm including 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 [June 2024 Drug Safety Update](#).

Information about these risks was publicised prior to the introduction of the PPP. An average GP practice within Cornwall and Isles of Scilly currently has 10 women who may require the PPP.

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 4 weeks after last dose (topiramate is an enzyme inducer that reduces effectiveness of hormonal contraceptives and there are limited options for HEC see [FSRH CEU Guidance: Drug Interactions with Hormonal Contraception \(May 2022\) | FSRH](#) point 9).
- 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](#)).

A Healthcare Professional's Guide to the PPP is available for [Epilepsy](#) and [Migraine Prophylaxis](#).

Topiramate is also used as an unlicensed treatment for idiopathic intracranial hypertension (IIH). These patients may or may not have a co-existing diagnosis of migraine.

Topiramate is now classified within the local formulary as specialist advised for migraine prophylaxis in women of childbearing potential and specialist initiated for epilepsy. Which means it should not be initiated in primary care for these indications without the advice of a specialist.

This update is summarised in a flow chart on page 6.

Practical Advice for Prescribers

ALL women of childbearing potential CURRENTLY Prescribed Topiramate:

- Identify all women and girls of childbearing potential age 12-55 yrs on topiramate. Clinical systems and Ardens have searches to do this.
- Ensure there is a correct read coded indication for topiramate within the clinical record. This will be epilepsy or migraine prophylaxis in most cases. Link this indication to the topiramate prescription template.
- 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 teams as appropriate to the indication.
- Provide those of childbearing potential with the appropriate Patient Guide [Epilepsy](#) or [Migraine Prophylaxis](#) for the PPP. Advise patients prescribed topiramate for epilepsy not to stop taking topiramate without the advice of a specialist as this will risk worsening epilepsy. Inform them

that as part of the new PPP measures either a healthcare professional from your practice or the specialist neurology service will discuss the PPP with them. This may be at their next review or sooner in some cases.

- Identify, and prioritise for documented discussion, those of childbearing potential who are not using HEC. Please see FSRH guidance which currently recommends limited options of Cu-IUD, LNG-IUS, DMPA plus condoms because topiramate is an enzyme inducer and may reduce the effectiveness of hormonal contraceptives see [FSRH CEU Guidance: Drug Interactions with Hormonal Contraception \(May 2022\) | FSRH](#) point 9. 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 should be an informed choice and discussions should be documented.
- If you consider there is a compelling reason that there is no potential for pregnancy and the topiramate PPP is not needed, complete “Step 1” on the ARAF. Add the read code “PPP not needed” (Y2f18) and save the ARAF in the clinical record. This must be revisited at least annually or sooner if the patient’s circumstances change.

Specific actions for those with an indication of epilepsy:

- Advise patients not to stop taking topiramate without the advice of a specialist as this will risk worsening epilepsy.
- Local epilepsy nursing service intend to complete the pregnancy prevention programme Annual Risk Awareness Form (ARAF) at the patient’s next review.
- Those who have been discharged from regular neurology follow up or who are not known to the service will need to be referred to the epilepsy service via (ERS) electronic referral system and highlight ‘Topiramate Pregnancy Prevention Programme’ as the reason for referral.
- Those who are still under the care of neurology for epilepsy but
 - Without clear next follow up or review date, send an email to department with subject “Topiramate PPP” as reason rcht.neurology@nhs.net with the subject “Topiramate PPP”.
 - With upcoming neurology appointments in the next 12 months, no further referral action required from GP.

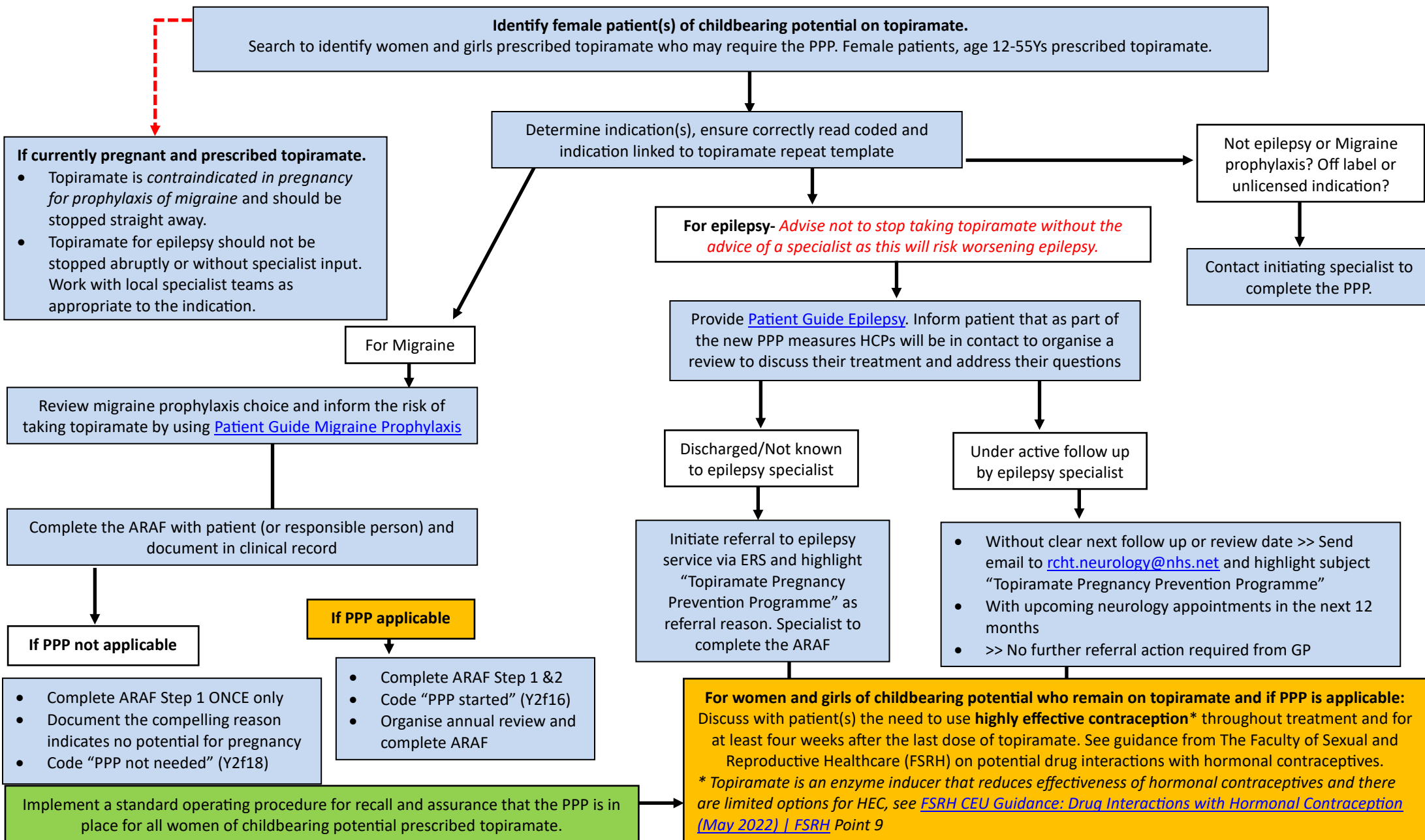
Specific actions for those with an indication of migraine prophylaxis:

- Do not routinely refer women of childbearing potential prescribed topiramate for migraine prophylaxis to the neurology/specialist teams.
- Consider if topiramate is still indicated/the best option for the patient. The headache pathway on RMS can be found here [Headache Management](#) and Migraine management on CKS [Scenario: Adults | Management | Migraine | CKS | NICE](#)
- If they are currently under follow up with the neurology team or you are unsure due to clinical complexity, please contact their specialist for advice.
- 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. Read code “PPP started” (Y2f16). 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.

Patients prescribed topiramate unlicensed for idiopathic intracranial hypertension

- Advise patients not to stop taking topiramate without the advice of a specialist as this may risk worsening IIH and papilloedema.
- Local neurology services intend to complete the Annual Risk Awareness Form at the patient's next review.
- Those who have been discharged from regular neurology follow up or who are not known to the service will need to be referred into the neurology service via the usual referral system and highlight 'Topiramate Pregnancy Prevention Programme' as the reason for referral.
- Those whose are still under the care of neurology for IIH but without clear next follow up or review date, send an email to department with subject "Topiramate PPP" as reason. With upcoming neurology appointments in the next 12 months, no further referral action required from GP.

For all women of childbearing potential prescribed topiramate: Implement a standard operating procedure for recall and assurance that the PPP is in place for all.



Resources

Ardens

- Report to identify patients in Prescribing | Alerts > Neurology
- Topiramate monitoring template
- Associated alert that will show on the patient's home screen that a drug review is required

SystemOne Alert

- SystemOne have published a nationwide pop-up following the updated MHRA alert. This alert will pop-up in the following circumstances:
 - When a topiramate medicine is prescribed as an acute or repeat
 - When a repeat template for topiramate medicine is issued
 - When a patient who has a current repeat topiramate medicine prescription record is retrieved

OptimiseRx pop up

For patients aged 10 to 54 years (inclusive), not recorded as of no childbearing potential, without a completed topiramate Annual Risk Awareness Form within 1-year, prescribed topiramate, a pop up will show from OptimiseRx.

Ensure a topiramate pregnancy annual risk awareness form has been completed (otherwise treatment is contraindicated).