

Topiramate Prescribing Safety Migraine Prophylaxis in Primary Care

(see also Grampian Guidance/ National Headache Pathways)

Topiramate is subject to Medicine and Healthcare products Regulatory Agency (MHRA) controls, due to concerns regarding safety in pregnancy and risks regarding significant harm to the unborn child.

These risks includes higher rates of congenital malformations, low birth weight and intellectual disability, autistic and attention deficit hyperactivity spectrum disorders in children of mothers taking topiramate during pregnancy.

Topiramate is now contraindicated in pregnancy, and in women of childbearing potential unless the conditions of a Pregnancy Prevention Programme are fulfilled.

The prescribing of topiramate to a woman of childbearing potential without the Pregnancy Prevention Programme (PPP) conditions being fulfilled is unlicensed, and it is recommended that clinicians follow the guidance below.

Practices should identify existing patients, woman of childbearing potential, prescribed topiramate and follow the information/flow chart to ensure compliance with MHRA controls.

- Women of childbearing potential, currently prescribed topiramate, for migraine, which was initiated by Primary Care will be monitored and reviewed in General Practice.
This includes:
 - Decision of whether to continue therapy, in discussion with the patient
 - Provision of Patient Guide
 - Completion of PPP and Annual Risk Assessment Forms (RAF)
 - Complex cases may be referred to Specialist Services if support is required e.g. consideration of alternative treatments, request for review.
- Women of childbearing potential, currently prescribed topiramate, for migraine, which was initiated by Specialist Headache Service may also be reviewed in Primary Care.
If necessary these patients may be referred back to the Specialist Service following provision of Patient Guide by Primary Care. Specialist Headache Service will then be responsible for:
 - Decision of whether to continue therapy, in discussion with the patient
 - Completion of PPP and Annual Risk Assessment Forms (RAF)
- Women of childbearing potential, prescribed topiramate for indications other than migraine should be referred to the appropriate speciality for review, PPP discussion and completion of Annual Risk Assessment Form (RAF).
- Primary Care should not initiate new topiramate treatment in women of childbearing potential, unless under the direct instruction of Specialist Services.

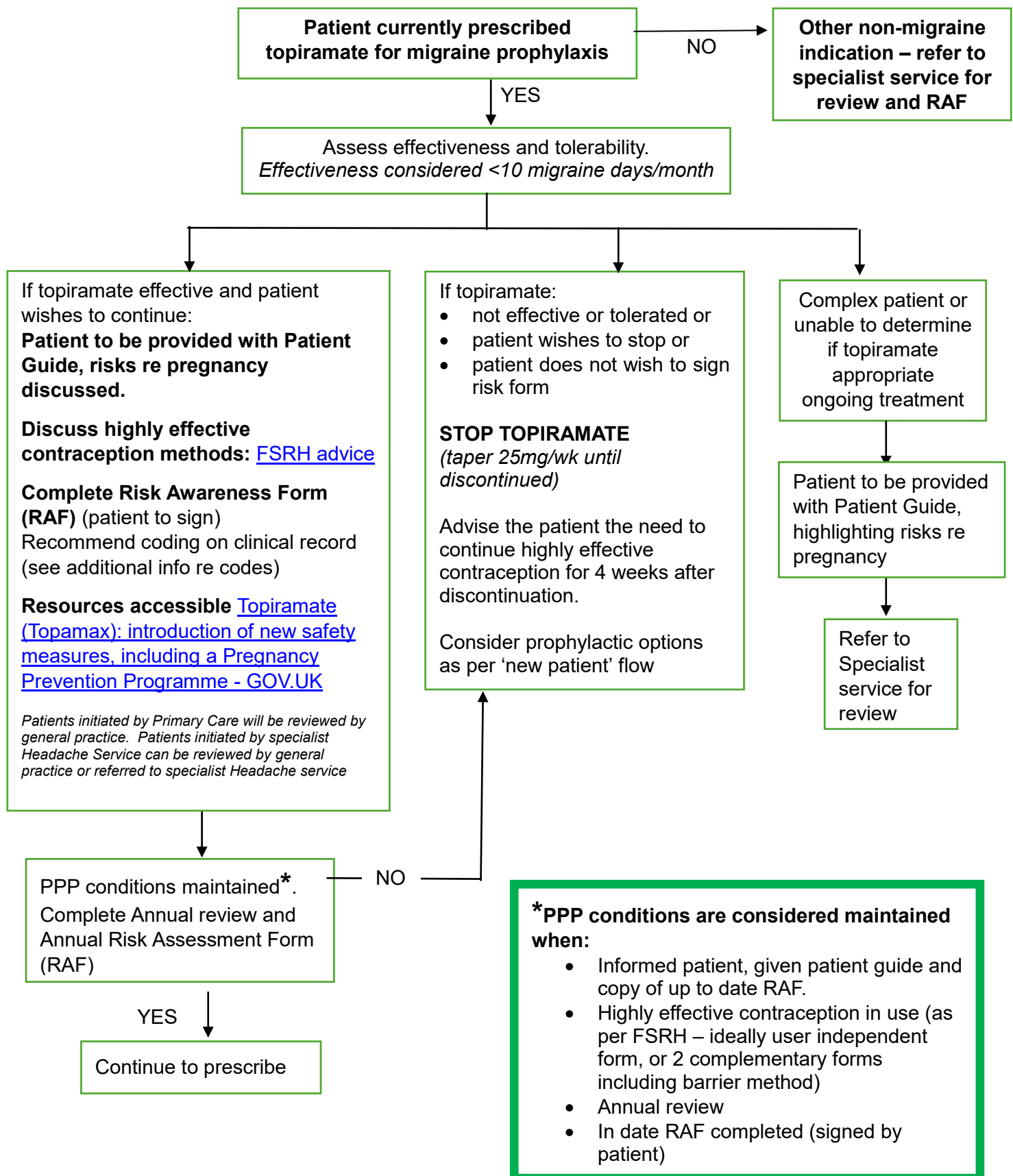
- The NHS Grampian formulary status for [topiramate](#) has been updated to classify topiramate as 'AMB1 – treatment may be initiated in Primary Care on the recommendation of a consultant/specialist'. The formulary status remains 'green' for men and women over 55 years of age 'can be initiated in either Primary or Secondary Care'.
- Specialist Services may recommend Primary Care prescribe topiramate for new women of childbearing potential, if clinically indicated. Specialist Services will be responsible for:
 - Initial discussion with patient re risk/benefit
 - Provision of patient guide
 - Provision of RAF, signed by patient
 - Completion of Annual review and Annual Risk Assessment Forms (RAF)

PPP conditions are applicable to female patients including those who are not sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy e.g. post-menopausal, hysterectomy. This should be documented on a signed RAF.

There are currently no additional precautions required for males prescribed topiramate.

This information has been developed by Medicines Management Team in collaboration with the Specialist Headache Service. This document has been reviewed by NHS Grampian Interface Group, GP Sub and approved by NHS Grampian Primary Care Prescribing Group.

Topiramate Review Flow Chart – Woman Child Bearing Potential



Summary of Migraine Treatments in Primary Care

New Patient requiring migraine prophylaxis

Trial of preventative therapy - considering contra-indications, comorbidities and interactions on an individual patient basis.

Options:

Propranolol 20mg twice daily (increasing by 20mg twice daily, fortnightly to 80mg twice daily or max tolerated dose)

Candesartan 4mg daily (increasing by 4mg fortnightly to 16mg daily or max tolerated dose)

Tricyclic – Amitriptyline/nortriptyline 10mg daily (increasing by 10mg weekly to min effective/tolerated dose – 30-50mg normal dosing/can increase upto 100mg if required)

Trial any preventative treatment for 10-12 weeks at an adequate dosage before considering ineffective.

Patients should record information in headache diary.

More than 10 migraine days a month

YES

NO

Preventative treatment ineffective – trial alternative.

If all appropriate primary care options trialled refer to headache clinic.

Preventative treatment effective, continue

If topiramate considered appropriate by specialist service they will discuss with the patient, complete the Initial Risk Assessment Form, provide patient guide and discuss contraception.

Further information on migraine treatment and prophylaxis available on Grampian Guidance:
[Headache - Migraine](#)

Primary Care to prescribe topiramate, at the request of headache clinic, and continue where PPP conditions are maintained*. Headache clinic will complete Annual reviews and Annual Risk Assessment Forms (RAF) on an ongoing basis.