NHS Somerset

Shared Care Protocol
*Topiramate for all patients (male or female) for all indications**

* This shared care protocol does not apply to patients who are prescribed topiramate for migraine prophylaxis, cluster & tension headache who are managed solely in primary care. In this instance, the GP who initiates the medication has total clinical responsibility for the drug and the consequences of its use, including fulfilling the requirements of the Pregnancy Prevention Programme.

This shared care protocol (SCP) sets out details for the sharing of care for ***all patients prescribed topiramate in the management of any indication (including off-label use).***

It should be read in conjunction with the latest Summary of Products Characteristics (SmPC) available at http://www.medicines.org.uk/emc/

As outlined in NHS England Guidance 2018 (07573), 'Responsibility for Prescribing Between Primary & Secondary/Tertiary Care': When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP concerned (and the patient) to share their care.

This document provides information on drug treatment for the shared commitment between the specialist and GP concerned. GPs are invited to participate. If the GP is not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

N.B. If the GP decides not to participate in shared care for a particular patient, they must inform the relevant specialist in writing, within 2 weeks of receipt of a request to share care.

Introduction:

Topiramate is now contraindicated in pregnancy and in females of childbearing potential unless the conditions of a Pregnancy Prevention Programme are fulfilled. This follows a review by the MHRA which concluded that the use of topiramate during pregnancy is associated with significant harm to the unborn child. Harms included a higher risk of congenital malformation, low birth weight and a potential increased risk of intellectual disability, autism and attention deficit hyperactivity disorder in children of mothers taking topiramate during pregnancy.

Topiramate is indicated for the prophylaxis of migraine and for the treatment of epilepsy. It is also sometimes used outside of the licence ('off label') to treat other conditions, such as intracranial hypertension, cluster and tension headache

MHRA/CHM advice:
Topiramate (Topamax): introduction of new safety measures, including a Pregnancy Prevention Programme - GOV.UK (www.gov.uk) Published 20 June 2024
Antiepileptic drugs in pregnancy: updated advice following comprehensive safety review - GOV.UK Published 7 January 2021
Antiepileptics: risk of suicidal thoughts and behaviour - GOV.UK Published 11 December 2014

Ethical considerations:

To fulfil legal, GMC, and Montgomery judgement informed choice principles, patients and/or carers must be given appropriate information regarding topiramate efficacy and safety in order to balance the risks and benefits and decide on the best treatment for them.

There are a number of innately complex practical and ethical considerations regarding topiramate use and the requirements of the Pregnancy Prevention Programme. In particular:

- People who are able to become pregnant and are unwilling to use long-term highly effective contraception for personal, religious, or health reasons.
- People who lack capacity.
- People with learning disabilities must not be presumed to not be sexually active.
- People with life-threatening symptoms that can only be controlled by topiramate.

For people who lack capacity to be involved in the decision-making process, the requirements of the Mental Capacity Act must be met. All patients should be reviewed by their specialist, who is responsible for assessing their capacity relating to decisions regarding choice of medication. Where appropriate the specialist should enter discussion with the GP regarding the patient's capacity and decisions relating to contraception and childbearing. If the patient lacks capacity, then the specialist is responsible for initiating a Best Interest Meeting/Process.

For circumstances in which a pregnancy prevention programme (PPP) is not appropriate, records must be kept of which decisions are taken, their justifications, and who was involved in decision-making. Completion of an Annual Risk Awareness Form is still required. Clinicians are advised to observe advice from their healthcare regulators for such ethical considerations to ensure they meet statutory duties and professional responsibilities.

If the patient does not need to be enrolled on the Topiramate Pregnancy Prevention Programme, the reasons why should be documented on the Annual Risk Awareness Form. The patient or responsible person should countersign the Annual Risk Awareness Form to confirm the exception is in place and that risks have been discussed.

If the absence of risk may change, the date for the next annual review should be documented and the patient, parent or carer asked to contact the specialist rapidly if the situation changes before that date.

Full details of the **Topiramate Pregnancy Prevention Programme** and the accompanying risk management materials are available from the MHRA website.

Topiramate (Topamax): introduction of new safety measures, including a Pregnancy Prevention Programme - GOV.UK

Available resources include:

- Patient Guide for Migraine and Epilepsy
- Guide for Healthcare Professionals for Migraine and Epilepsy
- Risk Awareness Form for Migraine and Epilepsy
- Patient Card

Licensed indications:

- Epilepsy
- Prophylaxis of migraine

Off-label use: restrictions and responsibilities still apply
Topiramate is not licensed for treatment of conditions other than epilepsy or migraine in the UK. However, it is sometimes used off-label (for example, in intracranial hypertension). All females of childbearing potential should meet the conditions of a Pregnancy Prevention Programme, irrespective of indication. All prescribers should be aware of their responsibilities when prescribing off-label.

Off-label or unlicensed use of medicines: prescribers' responsibilities - GOV.UK (www.gov.uk)

Dose (posology & method of administration):

Consult product literature for full details http://www.medicines.org.uk/emc/

Contra-indications:

For full details see individual SmPCs at http://www.medicines.org.uk/emc/

- Hypersensitivity to the active substance or to any of the excipients
- Prophylaxis of migraine
  - in pregnancy
  - in females of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled
- Epilepsy
  - in pregnancy unless there is no suitable alternative
  - in females of childbearing potential unless the conditions of the Pregnancy Prevention Programme are fulfilled

Special warnings and precautions:

For full details see individual SmPCs at http://www.medicines.org.uk/emc/

- Avoid in **acute porphyria**
- **Oligohydrosis (decreased sweating)** has been reported in association with the use of topiramate. Decreased sweating and hyperthermia (rise in body temperature) may occur especially in young children exposed to high ambient temperature.
- People at risk of **metabolic acidosis**.
- People at risk of **nephrolithiasis** — ensure adequate hydration (particularly when undertaking strenuous activity or in a warm environment).
- **Hepatic and renal impairment** — clearance of topiramate may be decreased, dose reduction may be required
- **Suicidal ideation and behaviour** – Patients/carers should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge - see MHRA alert Antiepileptics: risk of suicidal thoughts and behaviour - GOV.UK
- **Weight loss**: some patients may experience weight loss whilst on treatment with topiramate
- **Alcohol** intake is not recommended during treatment with topiramate.

Continuity of supply of a specific product

The MHRA classify topiramate medicines as a category 2 antiepileptic drug. When used for epilepsy, the need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with the patient and/or carer, considering factors such as seizure frequency and treatment history. See MHRA advice for more information. In case of availability problems, discuss with the specialist team for advice on the best course of action for the individual patient.

Drug interactions:

For full details see BNF and individual SmPCs at http://www.medicines.org.uk/emc/

- **Contraceptives**: Topiramate is an enzyme inducer that reduces effectiveness of hormonal contraceptives
    - Decreases the efficacy of combined hormonal contraceptives.
    - Predicted to decrease the efficacy of Drospirenone.
    - Predicted to decrease the efficacy of Desogestrel.
    - Predicted to decrease the efficacy of Etonogestrel (Nexplanon LARC).
    - Predicted to decrease the efficacy of Levonorgestrel.
    - Predicted to decrease the efficacy of Norethisterone.
    - Decreases the efficacy of Ulipristal (EllaOne EHC).

See FSRH Guidance: Drug Interactions with Hormonal Contraception (May2022).

- **Anti-seizure medicines:** concomitant use of multiple anti-seizure medicines may increase the risk of teratogenicity. Individual risk assessment is recommended.
- **Carbamazepine** - increased risk of toxicity

- **Phenytoin and fosphenytoin** – levels of phenytoin/ fosphenytoin and topiramate medicines may both be altered. Clinical monitoring recommended.
- **Valproate** – increased risk of toxicity when co-administered with topiramate, monitor for signs and symptoms of encephalopathy or hyperammonaemia
- **Alcohol or other central nervous system (CNS) depressants** — may have an additive effect.
- **Zonisamide** — increases the risk of overheating and dehydration. Manufacturer advises avoid in children.
- **Warfarin** — may lead to decreased prothrombin time/international normalized ratio (INR).

Fertility, pregnancy and lactation:

Pregnancy:
The use of topiramate during pregnancy is associated with significant harm to the unborn child (both from the confirmed risks of congenital malformations and low birth weight and the potential risk of neurodevelopmental disorders)

Females of childbearing potential taking topiramate should be 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.

If a patient becomes pregnant whilst on topiramate - immediately refer to a specialist to consider alternative treatment options.
Patients on topiramate must be informed to not stop taking their treatment without advice from their specialist.

Information for healthcare professionals:
https://uktis.org/monographs/use-of-topiramate-in-pregnancy/

Information for patients:
https://www.medicinesinpregnancy.org/leaflets-a-z/topiramate/

Breastfeeding:
Topiramate medicines are suitable for use in breastfeeding, but the conditions of the Pregnancy Prevention Programme must be met.

Topiramate passes into breast milk.
Infants should be monitored for adverse effects such as diarrhoea, drowsiness, irritability, adequate weight gain, and developmental milestones, especially in younger, exclusively breastfed infants and when using combinations of anticonvulsant or psychotropic drugs.
Topiramate may cause drowsiness, this will affect the safety of bedsharing, parents should have access to information to make safe choices, especially for caring for a baby at night. They should also be supported by the infant feeding team so they

know how to access support to establish feeding, which could be impacted if night feeds are missed during the first few weeks.

Information for patients: BASIS – Baby Sleep Information Source

Fertility:

There is no evidence to suggest that taking topiramate causes fertility problems in either men or women; however, topiramate should not be used if pregnancy is planned.

Information for patients:
Pregnancy, breastfeeding and fertility while taking topiramate - NHS

Adverse effects & management:

For full details and information on ADR's and incidence, see relevant SmPC's:
http://www.medicines.org.uk/emc/

- Nervous system disorders — cognitive impairment, confusion, dizziness, drowsiness, seizures, tremor, abnormal coordination, speech impairment, and abnormal sensation.
- Psychiatric disorders — anxiety, depression, suicidal ideation/behaviour, mood swings and sleep disorders.
- Respiratory disorders — cough, and dyspnoea.
- Gastrointestinal disorders — gastrointestinal discomfort, constipation, diarrhoea, vomiting, dry mouth, nausea, anorexia and altered taste.
- Renal disorders — nephrolithiasis.
- Skin disorders — alopecia, decreased sweating, pruritus, and rash.
- Eye disorders — topiramate has been associated with acute myopia with secondary angle closure glaucoma, uveitis, mydriasis, choroidal detachments, retinal pigment epithelial detachments, and macular striae.
- Metabolic disorders — metabolic acidosis.
    - Hyperammonemia with or without encephalopathy has been reported with topiramate treatment.
    - The risk is dose-related and appears to be more frequent when topiramate is used concomitantly with valproic acid.
    - In patients who develop unexplained lethargy or changes in mental status associated with topiramate monotherapy or adjunctive therapy, it is recommended to consider hyperammonemic encephalopathy and to measure serum ammonia levels.
- Musculoskeletal disorders — joint disorders, and muscle weakness.
- Haematological disorders — anaemia.
- Malaise.

Report any suspected adverse drug reactions, including any case of a pregnancy exposed to topiramate medicines, to the Yellow Card Scheme (see advice for reporting suspected adverse drug reactions from medicines taken during pregnancy). Should exposure occur, pregnancy outcomes should be monitored and reported.

This list is not exhaustive. The manufacturer's summary of product characteristics (SmPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Advice to patients & carers:

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- If they suspect there has been a **problem with their contraception** or they may be pregnant. This includes any vomiting or diarrhoea if taking oral contraception.
- If they are **planning a pregnancy/family**
- **Symptoms of metabolic acidosis** e.g. feel sleepy, lose your appetite and have an irregular heartbeat
- **Symptoms of hyperammonemic encephalopathy** e.g. difficulty thinking, remembering information, or solving problems, being less alert or aware, feeling very sleepy with low energy
- **Suicidal ideation or behaviour**.

The patient should be advised to:

- Report any side effects to their primary care prescriber.
- Not stop taking topiramate medicines without first discussing this with their doctor, especially if taking for epilepsy (risk of status epilepticus and sudden unexpected death in epilepsy (SUDEP)).
- Ensure other healthcare providers are aware of topiramate medicine use (for example, coagulation blood tests may be needed prior to surgery).
- Use an appropriate form of contraception, as agreed with their doctor/nurse/sexual health service
- Take a pregnancy test whenever they suspect there is a chance they could be pregnant. This includes:
  - Three weeks after starting a new method of contraception, particularly if there was any risk of pregnancy at the start of the new method
  - Whenever there is any reason to doubt that contraception has been effective, e.g. missed pill, broken condom, missed or late menstrual period
  - Whenever a health professional recommends or offers a pregnancy test
- See NHS advice on when to do a pregnancy test, and where to get one: https://www.nhs.uk/pregnancy/trying-for-a-baby/doing-a-pregnancy-test/
- Not drive or operate machines if topiramate affects their ability to do so safely. Patients with a diagnosis which affects their ability to drive must notify the Driver and Vehicle Licensing Agency (DVLA); see https://www.gov.uk/driving-medical-conditions
- Tell anyone who prescribes them a medicine that they are taking a topiramate medicine. Always tell a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.

Patient information:

Topiramate https://www.nhs.uk/medicines/topiramate/

Contraception Guide: https://www.nhs.uk/conditions/contraception/

Shared Care Responsibilities

Specialist responsibilities:

1. Assess the patient and provide diagnosis.
2. Consider & discuss the therapeutic options with the patient before prescribing topiramate.
3. Provide an appropriate patient information leaflet.
4. Provide a copy of the **Patient Guide** to all females of childbearing potential.
5. Fulfil responsibilities of **Topiramate Pregnancy Prevention programme.**
6. Ensure female patients of childbearing potential and/or their carer understand the risks relating to pregnancy exposure to topiramate.
7. Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see also '**Advice to patients & carers'**) to enable the patient to reach an informed decision. Counselling should include **the need for 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: Drug Interactions with Hormonal Contraception (May 2022) | FSRH point 9.
8. Obtain and document patient consent.
9. Assess the patient for contraindications, cautions and interactions
10. For all females of childbearing potential, complete the **Annual Risk Awareness Form** with the patient (or responsible person)
11. Ensure that pregnancy has been excluded, by means of a negative pregnancy test, prior to starting treatment with topiramate
12. Liaise with or refer to primary care or sexual health service to arrange for appropriate contraception.
13. Initiate and optimise treatment with topiramate. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
14. Once the specialist considers the patient's condition is stable or predictable and treatment is optimised, a request can be made to the patient's GP to 'share' the patient's care.

15. Notify the patient's GP that topiramate has been initiated – detailing the diagnosis, current and ongoing dose, any relevant test results and when the next review is required. Include a copy of the completed Risk Awareness Form and provide contact information for the specialist team.

16. Prescribe sufficient medication to enable transfer to primary care and inform patient/carer of the arrangements for further prescriptions.

17. Conduct the scheduled **reviews and monitoring.**
This includes:

    - Review of the clinical condition.
    - Review treatment with topiramate - decide with the patient whether topiramate continues to be the best treatment.
    - Completion of the **Annual Risk Awareness Form**
    - Discussion regarding contraception, including a prompt to check when long-acting reversible contraceptives (e.g. IUDs, IUSs, Medroxyprogesterone Depo injections as recommended. Note: Nexplanon efficacy may be affected by topiramate) must be renewed.

18. As per NICE guidance, conduct regular **(at least annual)** monitoring reviews for:

    - All children and young people with epilepsy.

    - Adults with epilepsy and any of the following:
        - a learning disability
        - drug-resistant epilepsy
        - a high risk of sudden unexpected death in epilepsy (SUDEP)
        - a serious comorbidity, such as complex psychosocial, cognitive or mental health problems
        - who are taking antiseizure medications associated with long-term side effects or drug interactions
        - who are able to get pregnant.

19. Discussions between clinicians and patients already on topiramate must include counselling on alternative treatment options and the benefits and risks associated with any change for patients with epilepsy; this should include a discussion of the risks of sudden unexplained death in epilepsy (SUDEP).

20. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined remains appropriate. **Provide a copy of the updated Annual Risk Awareness Form to primary care.**

21. All patients will remain under the ongoing care of a named consultant/specialist.

22. The specialist will reassume prescribing responsibilities and provide advice on alternative treatment options if a patient becomes or wishes to become pregnant.

23. The specialist will provide support if problems occur using the contact details provided

24. The specialist will reassume prescribing responsibilities should any problem occur, that cannot be readily corrected in primary care.

General Practitioner responsibilities:

1. For female patients of childbearing age, where shared care of topiramate is requested, ensure completed **Annual Risk Awareness Form** is received from specialist, this includes when a patient restarts topiramate after a period off topiramate.
2. For female patients of child-bearing age where shared care is requested, ensure patient has a **Pregnancy Prevention Plan** and is on highly effective contraception unless there are compelling reasons that the reproductive risks do not apply.
3. If the Annual Risk Awareness Form or Pregnancy Prevention Plan are absent, communicate back to specialist urgently requesting this information to enable GP to take over prescribing responsibility.
4. Accept request to take on prescribing of topiramate once the specialist considers a patient's condition is stable or predictable and treatment is optimised, no sooner than 4 weeks after initiation.
5. Ensure the patient's clinical records are coded appropriately, including a code for method of contraception.
6. Ensure patient has the **Patient Guide** and reinforce educational points provided by the specialist. See also **'Advice to patients & carers**
7. Ensure continuous use of **highly effective contraception** (HEC) in all females of childbearing potential. 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.
8. Ensure patient understands the need to comply with highly effective contraception throughout treatment with topiramate and undergo pregnancy testing when required e.g., if there is any reason to suggest lack of compliance or lack of effectiveness of contraception.
9. Remind the patient to contact you immediately if they suspect there has been a problem with their contraception or if they may be pregnant.
10. In case of female children using topiramate, remind the patient's responsible person to contact their GP once the patient using topiramate experiences their first period (menarche). Their GP will refer the patient back to the specialist.

11. Remind female patients of childbearing potential that they will need to discuss and complete the Annual Risk Acknowledgement Form with their specialist prescriber annually.
12. Inform the specialist of changes in the patient's medical condition and/or prescribed medication, especially adverse effects.
13. Check that all patients on the Topiramate Pregnancy Prevention Programme have an up to date, signed, **Annual Risk Awareness Form** when a repeat prescription is issued
14. Refer any patient planning to become pregnant to the specialist. Inform them to not stop using contraception or topiramate until told to do so by their specialist. Refer prescribing responsibilities back to the specialist.
15. Refer prescribing responsibilities back to the specialist if a patient becomes pregnant. If taking for epilepsy, advise the patient not to stop taking topiramate until told to do so by her specialist. For other indications, if clinically safe to do so e.g. migraine, topiramate can be stopped abruptly and symptoms managed with analgesia if patient becomes pregnant.
16. Adjust the dose of topiramate medicine prescribed as advised by the specialist.
17. For female patients of childbearing potential, ensure the patient remains under the care of the specialist, is seen by them annually for a review, and has an up to date Annual Risk Awareness Form on file at all times. This should be documented in the record with the SNOMED code Topiramate Pregnancy Prevention Programme Annual Risk Awareness Form completed (situation) SCTID: 2181271000000102
18. For female patients of childbearing potential, put in place a robust mechanism to ensure that the Annual Risk Awareness Form (ARAF) is in date when prescriptions are issued and to ensure that patients are recalled or referred back before the expiry date. However, a prescription for topiramate should not be stopped simply due to a delay in specialist review/ ARAF completion, as this may put the patient at risk.
19. Refer prescribing responsibility back to the specialist should problems arise that cannot be readily corrected, this includes when the specialist's responsibilities of the Topiramate Pregnancy Prevention Programme are not being fulfilled.

SNOMED codes available:

Pregnancy Prevention Programme SCTID 1129761000000105

Topiramate Pregnancy Prevention Programme Annual Risk Awareness Form completed (situation) SCTID: 2181271000000102

Topiramate Pregnancy Prevention Programme Annual Risk Awareness Form for Prophylaxis of Migraine (record artifact) SCTID: 2181261000000109

Topiramate Pregnancy Prevention Programme Annual Risk Awareness Form for Epilepsy (record artifact) SCTID: 2181251000000106

Pregnancy prevention programme not needed (situation) SCTID: 1129791000000104

Patient and/or carer responsibilities:

- Read and keep the Patient Guide, discuss and complete the appropriate Risk Acknowledgement Form with their specialist.
- Take topiramate medicines as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for review appointments with primary care prescriber and the specialist. Keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Attend annual review with specialist. Discuss and complete the Annual Risk Awareness Form with their specialist.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in 'Advice to patients & carers' section.
- Patients of child-bearing potential should use an appropriate form of contraception, as agreed with their doctor/nurse/sexual health service.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.
- Not to stop taking topiramate without advice from a healthcare professional, especially if taking for epilepsy.
- Report the use of any over the counter medications to their primary care prescriber and specialist, and be aware they should discuss the use of topiramate medicines with their pharmacist before purchasing any OTC medicines.
- Alcohol intake is not recommended during treatment with topiramate. Avoid recreational drugs.
- Not to drive or operate heavy machinery if topiramate affects their ability to do so safely. If unsure, talk to their doctor, pharmacist or healthcare professional.

Further support

- Contact specialist team via agreed channels.
- Prescribing & Medicines Management Team, NHS Somerset ICB
  Tel: 01935 384123 Email: somicb.medicinesmanagementteam@nhs.net

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	MH Drug & Therapeutics Committee, Somerset NHS FT	
Review by:		November 2027

References

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- Drugs for the prevention of migraine | Prescribing information | Migraine | CKS | NICE
- NICE guideline NG197 Shared decision making - Published 17 June 2021 https://www.nice.org.uk/guidance/ng197/
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