Amber with Guidance (Amber-G) = To be recommended or initiated by a specialist with follow up prescribing and monitoring by primary care clinicians.*
**Specialist is defined by the APC as a clinician who has undertaken an appropriate formal qualification or recognised training programme, or who has the appropriate knowledge and competencies within the described area of practice.*

NHS Barnsley Hospital NHS Foundation Trust | NHS South West Yorkshire Partnership NHS Foundation Trust | NHS South Yorkshire Integrated Care Board

Pregabalin for Generalised Anxiety Disorder

The details of side-effects, cautions, contraindications and interactions are not a complete list and the current BNF (https://www.medicinescomplete.com/#/) and the SPC (https://www.medicines.org.uk/emc/) remain authoritative.

Background Information	• Pregabalin can be used as a **third line option** for generalised anxiety disorder. • Local guidance places pregabalin **third line after SSRIs and SNRIs** (See Appendix A). NICE also recommend pregabalin in patients who do not respond to, or are unable to take SSRIs and SNRIs
BNF therapeutic class	Generalised Anxiety Disorder
Indication	Pregabalin is licensed for General Anxiety Disorder. Its other indications are Peripheral and Central Neuropathic pain, adjunctive therapy for partial seizures with or without secondary generalisations.
Dosage and administration	**Generalised anxiety disorder**: Adults over 18 years, initially 150 mg daily in 2 divided doses, increased if necessary at 7-day intervals in steps of 150 mg daily; max. 600 mg daily in 2 divided doses
Cautions and Contraindications	**Contraindications:** Hypersensitivity to active substance or excipients. **Cautions:** • **Consider the potential for dependence and misuse before prescribing pregabalin. Discuss the likely efficacy of pregabalin and also about the risk of harms, including dependence with the patient. Prescribe with caution in those with a history of substance misuse and if prescribed monitor for signs of abuse or dependence. Also consider the potential for illicit diversion either by choice or through coercion.** Pregabalin was reclassified as a Schedule 3 controlled drug in April 2019 due to concerns of potential for abuse and dependence: MHRA. • Conditions that may precipitate encephalopathy. • Diabetes Mellitus – due to potential weight gain. • Renal impairment – please refer to SPC if eGFR <60ml/minute. • Respiratory depression – respiratory or neurological conditions, impaired respiratory function, Taking other CNS depressants eg opiates and those with severe congestive heart failure. • Elderly patients • At risk of falls – can cause dizziness and somnolence. Post marketing reports of loss of consciousness, confusion and mental impairment. • **At risk of suicide – see monitoring section on follow up – small increased risk of suicide ideation & behaviours in people treated with antiepileptic drugs. Monitor at risk patients for increase in suicidal ideations.** • Constipation – post marketing reports of events related to reduced gastrointestinal tract function (obstruction, paralytic ileus and constipation) when pregabalin was co-administered with medications like opiates. During combination therapy, measures to prevent constipation should be considered, especially in women and elderly people.

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Pregnancy and breast feeding	**Pregnancy:** Pregabalin should not be used in women who are pregnant, unless the benefit to the mother clearly outweighs the potential risk to the foetus. **Breast Feeding:** Pregabalin is excreted into human milk. The effect of pregabalin on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue pregabalin therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
Adverse Drug Reactions	The most common side-effects include somnolence and dizziness. Other side-effects (less than 10%) include dry mouth, constipation, nausea, vomiting, drowsiness and insomnia.
Monitoring	As per NICE GAD guidelines review the effectiveness and adverse effects of the drug every 2-4 weeks during the first 3 months of treatment and 3 monthly thereafter. Dose adjustments may be required. Modest benefit is seen within 6 weeks and continues to increase over time.
Interactions	Can potentiate the sedative effects of CNS depressant medications. Use alongside opiates in particular can cause constipation, obstruction and paralytic ileus from post marketing research.
Additional information	See Appendix A for treatment algorithm (subject to any updates in the interim from guideline being written to being reviewed)
Ordering information	Controlled drug

Contact names and details

Contact Details	Telephone number	Email
Chris Lawson, Head of Medicine Optimisation, NHS South Yorkshire Integrated Care Board, Barnsley Place	01226433798	chris.lawson@nhs.net
Barnsley Single Point of Access (SPA)	01226 645000	
Patrick Cleary Lead Pharmacist	01226644339	patrick.cleary@swyt.nhs.uk

Equality and diversity

- NA

References

- NICE clinical guideline (CG13); 2020 Overview | Generalised anxiety disorder and panic disorder in adults: management | Guidance | NICE [Accessed 3/1/24].
- NICE CKS Generalised Anxiety Disorder; 2023 Pregabalin | Prescribing information | Generalized anxiety disorder | CKS | NICE [Accessed 3/1/24].
- Electronic Medicines Compendium; 2023 Pregabalin Milpharm 150 mg capsules, hard - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) [Accessed 3/1/24].
- Pregabalin (Lyrica), gabapentin (Neurontin) and risk of abuse and dependence: new scheduling requirements from 1 April 2019 Pregabalin (Lyrica), gabapentin (Neurontin) and risk of abuse and dependence: new scheduling requirements from 1 April - GOV.UK (www.gov.uk) [Accessed 5/3/24].

Development Process

This guidance has been produced by Patrick Cleary, lead pharmacist SWYFT following an AMBER-G classification status of Pregabalin by the Barnsley Area Prescribing Committee. This guideline was ratified by the Area Prescribing Committee on 14th February 2024.

Pregabalin for GAD Amber-G Guideline

Appendix A:

ALGORITHM FOR

PHARMACOLOGICAL THERAPY

OF GENERALIZED ANXIETY DISORDER

- **1st LINE SSRIs:** NICE CKS Feb 2023 recommend Sertraline as the first SSRI of choice.

  (PAROXETINE AND ESCITALOPRAM ARE LICENSED although the former is now non formulary locally. HOWEVER, OTHER SSRIs ARE ALSO USED and widely endorsed by NICE)

- **2nd LINE SNRIs**

  (DULOXETINE AND VENLAFAXINE HAVE LICENCE FOR GENERALISED ANXIETY DISORDER)

PLEASE ALSO NOTE THAT SSRIs/ SNRIs MAY TAKE UP TO 3 MONTHS TO HAVE A THERAPEUTIC EFFECT

IF ABOVE FAILS/ INTOLERABLE DUE TO SIDE-EFFECTS :

- **3rd LINE**
  PREGABALIN OR ANY OTHER DRUGS WITH SOME EVIDENCE-BASED EFFICACY, SUCH AS BUSPIRONE, IMIPRAMINE ETC.

Note:
- **BENZODIAZEPINES NOT RECOMMENDED FOR MORE THAN FOUR WEEKS – AVOID IF POSSIBLE**