This policy statement is approved by Halton, Knowsley, Liverpool, Southport and Formby, South Sefton, St Helens, and Warrington CCGs

Halton | Knowsley | Liverpool | Southport and Formby | South Sefton | St Helens | Warrington | West Lancashire

PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
REF: PS184 FINAL
APC BOARD DATE: 24 MAY 2017

NHS Pan Mersey Area Prescribing Committee

SAFINAMIDE (Xadago®▼)

AMBER

The Pan Mersey Area Prescribing Committee recommends the prescribing of SAFINAMIDE (Xadago®▼) following specialist recommendation in the management of mid to late stage Parkinson's disease.

FOLLOWING SPECIALIST RECOMMENDATION

Safinamide is licensed for the treatment of adult patients with idiopathic Parkinson's disease as add-on therapy to a stable dose of levodopa alone or in combination with other medicinal products for the treatment of Parkinson's disease in mid to late stage fluctuating patients.

The Pan Mersey Area Prescribing Committee recommends the prescribing of safinamide, following specialist recommendation only, in patients who have failed to respond to rasagiline and/or selegeline, or in whom these treatments are inappropriate or not tolerated, and in whom consideration is being given to prescribing non-oral therapies e.g. apomorphine.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

Version: 2.1
Review date: May 2019
(or earlier if there is significant new evidence relating to this recommendation)

SAFINAMIDE (Xadago®▼) for Parkinson's disease

EFFECTIVENESS[1,2,3] Safinamide has a novel mechanism of action, acting through both dopaminergic and non-dopaminergic pathways – it is a selective and reversible inhibitor of MAO-B, and also reduces glutamate release through selective sodium and calcium channel antagonism. It is not clear to what extent non-dopaminergic effects contribute to its overall effect. Two randomised, placebo-controlled trials of 24 week duration showed the change in on-time without troublesome dyskinesia was significant greater in safinamide (50mg or 100mg daily) groups than in placebo groups, with least squares mean treatment differences of 0.5-0.9 hours ($p=0.0054$ to $p<0.0001$).The EPAR for safinamide states that, whilst modest, the observed increase in the on-state of 0.5-1 hours was clinically relevant. There have been no head-to-head studies comparing safinamide to existing treatment options.	**SAFETY**[1] Safinamide is contraindicated in patients with severe hepatic impairment, albinism, retinal degeneration, uveitis, inherited retinopathy or severe progressive retinopathy or in those receiving concomitant treatment with another MAO inhibitor or pethidine. Serious adverse reactions are known to occur with the concomitant use of SSRIs, SNRIs, tricyclics and MAO inhibitors. Consult the SPC for advice about the management of patients on these treatments. Common adverse effects are insomnia, dyskinesia, somnolence, dizziness, headache, cataract, orthostatic hypotension, nausea and falls.
COST[4] Annual cost of treatment and comparators: **Safinamide 50-100mg daily: £897** Selegiline 5-10mg daily: £60.30 - £117.64 Rasagiline 1mg daily: £762.98 **Do not prescribe 2 x 50mg tablets to make 100mg dose – this doubles the cost.** It is not possible to quantify patient numbers, although communication with local specialists indicates low patient numbers anticipated.	**PATIENT FACTORS**[1] No dosage adjustment is required in patients with renal impairment or elderly patients, although experience in patients over 75 years of age is limited. No dosage adjustment is required in patients with mild hepatic impairment. The lower dose of 50mg/ day is recommended in patients with moderate hepatic impairment. For full prescribing information, the Summary of Product Characteristics should be consulted.

PRESCRIBING INFORMATION[1]

Treatment with safinamide should be started at 50mg/day, and may be increased as clinically appropriate to 100mg/day. Patients and carers should be informed of potential impulse control disorders that may occur during treatment, including cases of compulsions, obsessive thoughts, pathological gambling, increased libido, hypersexuality, impulsive behaviour and compulsive spending or buying. Treatment should be reviewed by the specialist if these effects are noticed.

IMPLEMENTATION NOTES

Treatment should only be recommended by specialists in the management of Parkinson's disease, which may include, but is not limited to, neurologists, gerontologists or GPs with a specialist interest. It is the responsibility of the specialist team to provide clear detailed information about the treatment regimen to the GP upon initiation and when any dose adjustments are made. Dose adjustments remain the responsibility of the specialist team throughout treatment. It is the responsibility of the initiating clinician to counsel patients about potential impulse control disorders.

REFERENCES

1. Summary of Product Characteristics. Xadago®▼ 100mg film-coated tablets (last updated on 18th May 2016), Profile Pharma Ltd. [Online]. Available at http://www.medicines.org.uk/emc/medicine/31917 Last accessed on 6th February 2017
2. Borgohain R, Szasz J, Stanzione P et al. Randomized Trial of Safinamide Add-On to Levodopa in Parkinson's Disease With Motor Fluctuations. Movement Disorders. 2014; 29(2): 229-237
3. Schapira A, Fox S, Hauser R et al. Safinamide add on to L-dopa: a randomized, placebo-controlled, 24-week global trial in patients with Parkinson's disease (PD) and motor fluctuations (SETTLE). 65th Annual Meeting of the American Academy of Neurology (AAN); March 16-23, 2013; San Diego Convention Centre, San Diego, CA, USA.
4. MIMS Online. Available at http://www.mims.co.uk/ Last accessed on 6th February 2017