Northumberland, Tyne and Wear NHS Foundation Trust

Pharmacological Therapy Policy Practice Guidance Note **Physical Health Monitoring of Patients Prescribed Antipsychotics and Other Psychotropic Medicines– V01**		
Date issued Issue 1 – **Oct 2017** **Issue 2 – Jul 2019**	**Planned Review** **Oct 2020**	**PPT-PGN-08** Part of NTW(C) 38 Pharmacological Therapy Policy

Author/Designation	**Claire Thomas – Deputy Chief Pharmacist**
Responsible Officer / Designation	**Tim Donaldson – Trust Chief Pharmacist**

Contents

Appendices, listed separate to PGN

Document No:	Description			
Appendix 2	Monitoring requirements for children and young people (<18 years) prescribed antipsychotics (except clozapine)			
Appendix 3	Guidelines for the Management of QTc Prolongation http://nww1.ntw.nhs.uk/services/index.php?id=5527&p=2780&sp=5478in Adults Prescribed Antipsychotics			
Appendix 4	Monitoring requirements for stimulants, atomoxetine and guanfacine			

1 Introduction

1.1 This practice guidance note (PGN) sets out the recommended physical health monitoring for all Northumberland, Tyne and Wear NHS Foundation Trust (the Trust/NTW) patients prescribed psychotropic medicines. It incorporates the relevant NICE guidance and recommendations within the LESTER tool

1.2 This PGN provides a recommended standard for the majority of patients. The monitoring recommendations are split into children under 18 and all adults 18 and over. However, monitoring should be tailored to each patient. Patients may require more frequent monitoring e.g. those patients with increased cardiac risk.

2 Related/Associated Documents

2.1 The guidance should be read in accordance with the Trust's policy, NTW(C) 29 - Trust Standard for the Assessment and Management of Physical Health Monitoring. This gives guidance on how tests should be undertaken and what to do with abnormal results.

2.2 For patients prescribed high dose antipsychotics (i.e. receiving a cumulative antipsychotic dose of greater than 100% of BNF maximum) please read – NTW(C) 38 – Pharmacological Therapy Policy, practice guidance note – PPT-PGN-10 - Guidelines for the Use of Combination and High Dose Antipsychotics.

3 General Principles

3.1 When an NTW prescribing clinician prescribe a psychotropic medicines it is their responsibility to ensure that all relevant physical health monitoring has been undertaken and to consider the results of these on the patient's treatment.

3.2 Recording of results from investigations should be in accordance with Trust's recommendations with Trust policy NTW(O)09 – Management of Records, practice guidance note, RM-PGN-02 - Record Keeping Standards

3.3 The clinical team must take appropriate action for all results outside of normal range. Consideration should also be given to previous results that might have recently been undertaken by individuals before ordering or authorising new investigations, where applicable.

3.4 Where an examination or test is not or could not be undertaken, the reasons for this must be clearly documented in the patient's electronic care record. The tests should be performed as soon as possible.

3.5 In the event of a patient refusing such tests, this must also be clearly documented. The patient should be asked regularly about these tests and if they agree, they should be performed as soon possible.

3.6 Baseline Monitoring

3.6.1 The relevant baseline physical health monitoring should be undertaken by the clinical team before the initial prescription of a drug. If this is not possible this must be completed within the first 14 days of treatment.

3.7 Ongoing monitoring

3.7.1 A clear plan for the monitoring required for a patients medication must be documented in the patients electronic care record. This should detail what monitoring is required and how this monitoring will be undertaken. This plan must be communicated to the patients GP.

3.7.2 For patients prescribed antipsychotics the CPA review must consider the patients physical health and the results of any monitoring undertaken either by NTW or primary care.

3.8 Shared care

3.8.1 It is important that prescribers know the shared care status of the drugs they prescribe and have read the relevant guidance or information leaflets which detail specific information about the transfer of prescribing and monitoring responsibilities.

3.8.2 The trust intranet has general information about shared care and links to the relevant shared care agreements and information leaflets for the local CCG prescribing committees.
http://nww1.ntw.nhs.uk/services/index.php?id=5527&p=2780&sp=5478

3.8.3 Drugs prescribed outside of their licensed dose or indications are not covered by shared care agreements. The NTW prescriber maintains full responsibility for prescribing and monitoring for these patients. Where shared care agreements are in place, the responsibilities for prescribing and the associated monitoring may be transferred to primary care in line with the existing local agreement.

3.8.4 In communication with the accepting GP, it is essential that all results of any monitoring undertaken by NTW and the plan for ongoing monitoring must be included. (i.e. – when the next monitoring is due, who will carry this out (NTW / GP)) If results are not communicated this could result in the GPs refusing to enter into the shared care agreement for a particular patient.

3.9 Family planning and effective contraception for women

3.9.1 Deciding to have a baby is one of the most important choices a woman will make. For women with mental health problems there are many issues to consider, not least avoiding unplanned pregnancies.

Offering information about the full range of contraceptives available, including long-acting reversible contraception, will ensure women asking for routine or emergency contraception can make an informed choice.

Helping women choose the method of contraception that suits them best, and increasing their awareness of how to use contraceptives effectively, will help to reduce unplanned pregnancies.

Prescribers should discuss the following topics with patients and relevant family members/care-givers:

- Assess the most appropriate timing to discuss family planning (in the context of mental health) and provide general advice on effective contraception methods and refer your patient to a specialist if needed.
- Discuss the most effective method of contraception that best suits the patient's individual needs and lifestyle, so making it more likely that they will use contraception and use it effectively.
- Consider NICE Guidance recommending long-acting reversible contraception (which is of particular benefit where the risks of an unplanned pregnancy are high).
- Ensure your patient understands the importance of using contraception to avoid unplanned pregnancy (particularly for conditions at significant risk of perinatal relapse/exacerbation)
- Advise your patient to contact you immediately if she thinks she might be pregnant or becomes pregnant.
- Ensure women asking for emergency contraception are told that an intrauterine device (IUD) is more effective than an oral method. Also, once in place, it can be used on an ongoing basis. If women use an IUD this will reduce the risk of unplanned pregnancies and avoid the need for emergency contraception.
- If a woman chooses to have an IUD as a form of emergency contraception, but the healthcare practitioner cannot fit it there and then, they should direct the woman to a suitable service and give her an oral method in the interim.

Further guidance on the full range of effective contraceptive methods to be offered can be obtained from NICE (Public Health guideline PH51: Contraceptives services for under 25s, Clinical Guideline CG30: Long-acting reversible contraception and QS129 Contraception) and the Faculty of Sexual and Reproductive Healthcare guidelines (https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/).

4 Antipsychotics

Life expectancy in people with schizophrenia is reduced by 20%, with 60% of the excess mortality due to physical illness. This may be partly explained

by the higher prevalence of smoking, poor diet and lack of exercise in people with schizophrenia than in the general population; as a consequence the prevalence of type-2 diabetes and cardiovascular disease are increased. In addition to lifestyle factors, the illness itself may be a risk factor for such medical conditions: an association between schizophrenia and diabetes is well recognised. There is also concern that some antipsychotic drugs, particularly the second generation drugs, have metabolic consequences that contribute to these risks. Atypical antipsychotics are known to cause weight gain and have a negative impact on the lipid profile. They may also have a direct effect on insulin function, independent of weight gain. Metabolic effects are also seen in patients prescribed typical antipsychotics. However, it has also been shown that taking antipsychotics was associated with a lower hazard ratio of dying and clozapine is associated with the greatest risk reduction in the risk of dying despite having the worst metabolic profile (Tihonen et al)

The Lester Positive Cardiometabolic Health Resource http://www.rcpsych.ac.uk/quality/nationalclinicalaudits/schizophrenia/nationalschizophreniaaudit/nasresources.aspx#LesterResource provides practitioners with a simple assessment and intervention framework to protect the cardiovascular and metabolic health of patients with severe mental illness receiving antipsychotic medication. All patients prescribed antipsychotics or mood stabilisers should be monitored in accordance with the Lester tool.

4.1 Choice of Antipsychotic treatment

Prescribers must consider all relevant physical health issues including the patient's cardiovascular risk when choosing an antipsychotic.

4.2 Recommended monitoring

4.2.1 The recommended monitoring for the antipsychotic drugs is detailed in Appendix 1 for adult patients and table 2 for those under 18 years of age. The suggested monitoring recommendations are not exhaustive and are not intended to provide treatment recommendations for individual patients. Frequency of monitoring and additional monitoring where necessary should be specified based on individual risk factors, co-morbidities and physical health conditions. For the monitoring requirements of clozapine please see Trust policy PPT-Safe Prescribing of Clozapine - V02 - Issue 3 - May 17 - PPT-PGN-05 - NTW(C)38

4.2.2 When starting a patient on antipsychotic treatment, baseline monitoring must be undertaken by the clinical team before the initial prescription of an antipsychotic drug. (See appendix 1 and 2 for details of monitoring). If this is not possible this must be completed within the first 14 days of treatment.

4.2.3 NTW should maintain responsibility for monitoring the patient's physical health and the effects of antipsychotic medicines for at least the first 12 months of treatment or until the patient's condition has stabilised whichever is longer. Thereafter the responsibility for this monitoring may be transferred to primary care under shared care arrangements.

4.3 Weight gain with antipsychotics

4.3.1 Before starting a patient on antipsychotic treatment, the prescriber must inform the patient about the risk of weight gain and how to manage this. A record of the conversation must be documented in the patient's process notes on RiO.

4.3.2 The patient should then be weighed weekly for the first six weeks of treatment and any increase in weight should prompt further discussion around weight management. This is important because the greatest degree of weight gain is observed in the first six weeks of antipsychotic treatment and has been shown to predict overall total weight gain at two year follow-up.

4.3.3 Information to give patients includes the RSPsych information leaflet on managing weight gain (Insert hyperlink). In addition to this, the patient should be informed of local services and support, including a referral to Exercise Therapy where available. If either of these steps are delegated to another member of the MDT, it remains the responsibility of the prescriber to ensure that they are followed through.

4.4 Switching antipsychotic drugs

4.4.1 When switching from one antipsychotic drug to another antipsychotic, baseline monitoring must be repeated. However if the patient has recent clinically appropriate results these may be considered instead of repeating the tests. The responsibility for determining the clinical appropriateness of recent tests lies with the prescribing clinician.

4.5 Specific patient populations

4.5.1 Learning disabilities

4.5.1.1 People with a learning disability and/or autism occasionally receive a psychotropic medication to control challenging behaviour in line with NICE NG11 guidance 'The control of challenging behaviour in people with a learning disability' and NICE CG142 /CG 170 'Autism spectrum disorders in adults and children/young people'. If antipsychotic medicines are prescribed, even at lower doses, baseline monitoring must be carried out in line with this policy. It is the responsibility of the initiating team to ensure the baseline monitoring is completed.

4.5.1.2 Monitoring is of greater significance in this client group as they often have an increased physical health burden and a reduced life expectancy. Many have co-morbid mental health illness and epilepsy.

4.5.1.3 In primary care GPs are targeted to carry out an Annual Learning Disability Health Check which will encompass the required monitoring for those patients receiving a psychotropic medicine both for a mental health condition and/or the control of challenging behaviour (this includes a physical check as well as blood monitoring).

4.5.1.4 People with a learning disability often refuse regular monitoring especially blood testing. Some staff within the Trust are trained in desensitisation techniques to facilitate the monitoring process.

4.5.2 Children and Young People

4.5.2.1 Children and adolescents are at greater risk than adults of side effects such as EPSEs, hyperprolactinaemia, sedation, weight gain and metabolic effects. Therefore it is very important to monitor the physical health of these patients even when prescribed low doses.

4.5.2.2 Olanzapine should be avoided in the treatment of children and adolescents due to its high propensity for weight gain. (Kryzhanovskaya LA, Xu W, Millen BA et al. (2012) Comparison of long-term (at least 24 weeks) weight gain and metabolic changes between adolescents and adults treated with olanzapine. Journal of Child and Adolescent Psychopharmacology 22: 157–65).

4.5.3 Management of behavioural and psychological symptoms of dementia (BPSD)

4.5.3.1 The baseline monitoring requirements apply to the use of low-dose antipsychotic treatment for the management of behavioural and psychological symptoms of dementia (BPSD). It is the responsibility of the initiating team to ensure the baseline monitoring is completed.

4.5.3.2 In primary care GPs carry out an annual check for patients with dementia which encompasses the required ongoing monitoring for patients prescribed low-dose antipsychotic medicines. This includes a physical check as well as blood monitoring.

4.5.3.3 The use of antipsychotics for this indication must be regularly reviewed.

4.5.4 Management of acute anxiety by Crisis teams

4.5.4.1 In some services/ situations (e.g. Crisis Home Treatment Services) low-dose short-term prescribing of antipsychotics is used as an alternative to other supportive sedative medication choices such as time-limited Diazepam/ Lorazepam prescribing for severe anxiety/ agitation. This might be in a situation where benzodiazepine and related medications are contraindicated, not tolerated or there are potential interactions with other medications/ substances of misuse. The use of low-dose short term antipsychotics in these circumstances is off-licence. If an antipsychotic is prescribed at these low-doses for less than two weeks then, unless there are other clinical indicators to suggest otherwise, referral in for full antipsychotic screening and monitoring will not usually be required.

4.5.4.2 A referral for appropriate physical health screening should be made at the earliest opportunity in the following circumstances:

- When it becomes clear that prescribing is likely to last longer than 2 weeks

- If prescribing above the recommended low-dose limits is implemented
- If concerns around physical health issues or medication interactions are noted

5 Mood stabilisers

Patient prescribed mood stabilisers must have regular monitoring in line with the Lester Tool. The table below lists the additional medicines specific monitoring required.

Drug	Monitoring
Lithium	Refer to PPT-Safer Lithium Therapy PGN - V03 - Iss2-RepairLink-Apr16 - NTW(C)38 - PPT-PGN-19
Valproate	Refer to PPT-PGN-25 Safer Valproate Therapy *(under development)*
Lamotrigine	Baseline FBC, U&Es, LFTs No regular monitoring required Do not routinely measure plasma lamotrigine levels unless there is evidence of ineffectiveness, poor adherence or toxicity
Carbamazepine*	Baseline FBC, U&Es, LFTs Regular plasma level monitoring is not recommended and should only be done if clinically indicated (e.g. for detection of non-adherence, suspected toxicity, concomitant use of liver enzyme-inducing drugs) Patients or their carers should be told how to recognise signs of blood, liver or skin disorders, and advised to seek immediate medical attention if symptoms such as fever, rash, mouth ulcers, bruising or bleeding develop Consider vitamin D supplementation for people who immobilised for long periods of time or who have inadequate sun exposure or dietary intake of calcium
Oxcarbazepine*	No regular monitoring required
Levetiracetam*	No regular monitoring required
Topiramate*	No regular monitoring required

***Not recommended by NICE as mood stabilisers in Bipolar Disorder**

6 Antidepressants

6.1 General principles for monitoring all antidepressants

6.1.1 Hyponatremia

Hyponatremia (usually in the elderly and possibly due to inappropriate secretion of antidiuretic hormone) has been associated with all types of antidepressants; however, it has been reported more frequently with SSRIs than with other antidepressants. Hyponatremia should be considered in all patients who develop drowsiness, confusion, or convulsions while taking an antidepressant

6.1.2 Suicidal behaviour

The use of antidepressants has been linked with suicidal thoughts and behaviour; children, young adults, and patients with a history of suicidal behaviour are particularly at risk. Where necessary patients should be monitored for suicidal behaviour, self-harm, or hostility, particularly at the beginning of treatment or if the dose is changed

6.1.3 Serotonin syndrome

- Serotonin syndrome or serotonin toxicity is a relatively uncommon adverse drug reaction caused by excessive central and peripheral serotonergic activity. Onset of symptoms, which range from mild to life-threatening, can occur within hours or days following the initiation, dose escalation, or overdose of a serotonergic drug, the addition of a new serotonergic drug, or the replacement of one serotonergic drug by another without allowing a long enough washout period in-between, particularly when the first drug is an irreversible MAOI or a drug with a long half-life. Severe toxicity, which is a medical emergency, usually occurs with a combination of serotonergic drugs, one of which is generally an MAOI.
- The characteristic symptoms of serotonin syndrome fall into 3 main areas, although features from each group may not be seen in all patients—neuromuscular hyperactivity (such as tremor, hyperreflexia, clonus, myoclonus, rigidity), autonomic dysfunction (tachycardia, blood pressure changes, hyperthermia, diaphoresis, shivering, diarrhoea), and altered mental state (agitation, confusion, mania).
- Treatment consists of withdrawal of the serotonergic medication and supportive care; specialist advice should be sought.

6.2 Monitoring of specific antidepressants

6.2.1 **Agomelatine**

Test liver function before treatment and after 3, 6,12 and 24 weeks of treatment, and then regularly thereafter when clinically indicated (restarting monitoring schedule if dose increased); discontinue if serum transaminases exceed 3 times the upper limit of reference range or symptoms of liver disorder (Information leaflet for Primary Care available www.northoftyneapc.nhs.uk/guidance)

6.2.2 **Venlafaxine**

All patients should be carefully screened for high blood pressure and pre-existing hypertension should be controlled before initiation of treatment. Blood pressure should be reviewed periodically, after initiation of treatment and after dose increases.

Where doses over 225mg/day are used, blood pressure should be monitored regularly. There are no guidelines available as to specific frequency of monitoring, but based on available studies where dose-related increases have occurred, it has been suggested blood pressure and heart rate are monitored at 4 weeks, 8 weeks and 12 weeks and then if stable 6 monthly thereafter for doses over 225mg/day (Information leaflet for Primary Care available www.northoftyneapc.nhs.uk/guidance)

6.2.3 **Citalopram and Escitalopram**

- Baseline ECG, U&Es and Magnesium (Mg)

  Baseline tests and annual monitoring of serum magnesium **is only advised for at risk groups** i.e. those patients who are aged over 65 years OR are malnourished (BMI less than 18kg/m^2 AND are taking a diuretic or a proton pump inhibitor.

- Electrolyte disturbances such as hypokalaemia and hypomagnesaemia increase the risk for malignant arrhythmias and should be corrected before treatment with citalopram is started.

- If cardiovascular symptoms, such as palpitations, vertigo, syncope, or seizures develop during treatment, cardiac evaluation including ECG should be undertaken.

- Citalopram and escitalopram have been found to cause a dose-dependent prolongation of the QT-interval. Their use is contraindicated in patients with known QT-interval prolongation and should be used in caution in people susceptible to QT-interval prolongation. Also, the concomitant administration of drugs that prolong QT-interval should be avoided.

- Caution is advised in patients with significant bradycardia; or in patients with recent acute myocardial infarction or uncompensated heart failure.

- ECG monitoring may be advisable in case of overdose or conditions of altered metabolism with increased peak levels, e.g. liver impairment.

6.3 Discontinuation of antidepressants

Venlafaxine, duloxetine and paroxetine are associated with a higher incidence of discontinuation symptoms than other antidepressants.
Gastro-intestinal disturbances, headache, anxiety, dizziness, paraesthesia, tremor, sleep disturbances, and sweating are the most common features of withdrawal if treatment is stopped abruptly or if the dose reduced markedly.
Withdrawal effects may occur within 5 days of stopping treatment with antidepressant drugs; they are usually mild and self-limiting, but in some cases may be severe. The risk of withdrawal symptoms is increased if the antidepressant is stopped suddenly after regular administration for 8 weeks or more. The dose should preferably be reduced gradually over about 4 weeks, or longer if withdrawal symptoms emerge (6 months in patients who have been on long-term maintenance treatment).

7 Drugs used to manage ADHD (children and adults)

Please refer to Appendix 4 (insert link) for the monitoring requirements for stimulants, atomoxetine and guanfacine.

8 Melatonin

For the treatment of sleep-wake cycle disorders in children and young people with the aims of improving the onset and duration of sleep and establishing a regular nocturnal sleep pattern where non-pharmacological treatments have failed or are inappropriate.

Assess and monitor patients' response to treatment and the need to continue therapy on a 6-12 monthly basis.
Monitor:

- Height
- weight
- sexual development

9 Useful resources

- Lester UK Adaptation Positive Cardiometabolic Health Resource - http://www.rcpsych.ac.uk/quality/nationalclinicalaudits/schizophrenia/nationalschizophreniaaudit/nasresources.aspx#LesterResource

- Rethink – physical health resources for health professionals - https://www.rethink.org/about-us/health-professionals/physical-health-resources

10 References

- Tiihonen J et al - 11-year follow-up of mortality in patients with schizophrenia: a population-based cohort study (FIN11 study) The Lancet, Volume 374, Issue 9690, Pages 620 - 627, 22 August 2009

- Maudsley Prescribing Guidelines 12th Edition 2015

- SPC of individual medicines, available at www.medicines.org.uk
- BNF 72, September 2016 – March 2017
- Royal College of Psychiatrists Consensus Statement on high dose antipsychotic prescribing May 2006
- Lester UK Adaptation Positive Cardiometabolic Health Resource http://www.rcpsych.ac.uk/quality/nationalclinicalaudits/schizophrenia/nationalschizophreniaaudit/nasresources.aspx#LesterResource
- Zipursky R et al - Course and predictors of weight gain in people with first-episode psychosis treated with olanzapine or haloperidol. The British Journal of Psychiatry, Volume 187, Issue 6, Pages 537-543, November 2005
- NICE Bipolar disorder – assessment and management CG185