Lancashire Care NHS
NHS Foundation Trust

Guidance for Prescribing Second Generation Long Acting Antipsychotic Injections

Introduction

The purpose of this guidance is to provide clarity on the approval process for the prescribing of the second generation antipsychotic long acting injections within Lancashire Care NHS Foundation Trust.

Current Formulary Status

This guidance covers the following preparations which have been recommended by the Lancashire Medicines Management Group (LMMG) and are commissioned by our Clinical Commissioning Groups (CCGs).

The following Second Generation Antipsychotics LAIs have been approved for use within the Trust: -

- Existing patients on Risperidone but no new approvals after June 2016
- Paliperidone palmitate
- Aripiprazole prolonged release suspension

All the second generation are currently RAG rated as RED which means that they cannot be passed back to the GP for prescribing and are not covered by the Shared Care Prescribing arrangements for Antipsychotics.

This guidance supports prescribing in line with the following recommendations of the NICE Clinical Guideline 178::

- The choice of antipsychotic medication should be made by the service user and healthcare professional together, taking into account the views of the carer if the service user agrees.
- Consider offering depot /long-acting injectable antipsychotic medication to people with psychosis or schizophrenia:
  - who would prefer such treatment after an acute episode
  - where avoiding covert non-adherence (either intentional or unintentional) to antipsychotic medication is a clinical priority within the treatment plan.
- When initiating depot/long-acting injectable antipsychotic medication:
  - take into account the service user's preferences and attitudes towards the mode of administration (regular intramuscular injections)
- Offer clozapine to people with schizophrenia whose illness has not responded adequately to treatment despite the sequential use of adequate doses of at least 2 different antipsychotic drugs. At least 1 of the drugs should be a non-clozapine second-generation antipsychotic

Approval process

Approval to prescribe for individual patients must be obtained prior to prescribing and initiation of treatment for the above LAIs.

The approval process will aim for completion within seven working days.

Where approval may be required as an emergency e.g. transfer of existing patients into LCFT who are prescribed any of the above products the Chief Pharmacist and Deputy Medical Director should be contacted.

A six month review form will be issued to Consultants providing information on response to the SGA LAI

Criteria

The following criteria are provided as a guide to inform the application and approval process

- Is there evidence of intentional non-adherence?
- Where there is unintentional non adherence have alternative strategies been put in place to promote adherence?
- Has the patient expressed a preference for a LAI above oral medication?
- Has the patient been prescribed a FGA long acting injection or is clearly expressing a preference for a SGA LAI?
- Has the patient experienced intolerable side effects with an FGA long acting injection?
- Has the patient experienced intolerable side effects with an oral FGA?
- Is the patient currently prescribed the oral antipsychotic linked with the LAI being requested?
    - Risperidone oral for Paliperidone (licensed indication see SPC) https://www.medicines.org.uk/emc
    - Aripiprazole for Aripiprazole LAI (licensed indication see SPC)
- Has the patient exhibited a positive therapeutic response to oral aripiprazole or oral risperidone?
- Does the patient fulfil the criteria for prescribing clozapine as defined in the NICE Clinical Guideline 178

- Are there significant risk factors associated with non-adherence e.g. forensic issues, child protection, court orders, previous history of violence

Where patients are transferred to the Trust and are maintained on treatment, supply will continue. An email will be sent with patient details to ensure a complete database of patients prescribed SGA LAIs. A clinical review will consider whether ongoing treatment is clinically indicated.

Approval

Approval will be based on the following: -

- The patient fulfils the criteria in the NICE guidance 178 for the prescribing of a LAI

- The patient has previously been prescribed a FGA LAI or a FGA LAI has been discussed as an option with the patient and the patient will not accept a FGA LAI
- The patient has experienced intolerable side effects to a FGA LAI or oral FGA, is expressing a clear preference for a SGA LAI, or has a history of positive response to oral aripiprazole or risperidone and the consultant psychiatrist therefore deems a SGA LAI the most appropriate pharmacological option for the patient
- The patient does not fulfil the criteria for prescribing clozapine or clozapine has been discussed with the patient and they are adamantly refusing to accept treatment or clozapine is contraindicated
- The prescribing is within the licensed indications (maintenance treatment of schizophrenia) or is prescribed for a schizophreniform disorder (schizoaffective disorder)
- The prescribing is for bipolar disorder (NICE recommendation) and there is a history of poor adherence with oral antipsychotic treatment
- The patient has been prescribed the oral therapy required as outlined in the SPC

All patients where approval is given will require a six monthly update report in respect of outcomes to enable audits to take place. This should include an indication of any re-admissions during the period when the depot was prescribed and an indication of adherence with the depot injection.

Paliperidone Long Acting Injection

- This product does not require refrigeration
- The injection is administered on a monthly basis
- The first initiation dose of 150mg should be administered into the deltoid muscle as this promotes faster attainment of therapeutic blood levels with a subsequent injection of 100mg on day 8 into the deltoid muscle
- Subsequent injections may be administered into either the gluteal or deltoid muscle.
- The usual maintenance dose is 75mg monthly with a possible dose range of 25mg to 150mg based on individual tolerability and efficacy.
- Dose adjustments can be made monthly however the full effect of the maintenance dose may not be seen for several months.
- There is no requirement to maintain oral therapy alongside the administration of the LAI

- Further advice is available when switching from risperidone LAI and where patients are currently prescribed oral and a depot this should be considered as Paliperidone allows for a higher therapeutic dose to be achieved. (See SPC link above for advice on switching)
- For maintenance treatment the monthly dose can be administered either seven days before or seven days after the four weekly due date.
- The median time to maximum plasma level is 13 days
- Patients who are adequately treated with 1-monthly paliperidone palmitate injectable (preferably for four months or more) and do not require dose adjustment may be switched to an equivalent three-monthly dose (cost-neutral) if clinicians feel this is clinically appropriate and the patient consents.

Aripiprazole Prolonged Release Suspension

- This product does not require refrigeration
- The injection is supplied as a freeze dried powder with a solvent for reconstitution, on reconstitution each ml contains 200mg
- Tolerability with oral aripiprazole must take place prior to administration of the LAI
- The recommended starting dose is 400mg
- The recommended maintenance dose is 400mg so no titration is required.
- Treatment with oral aripiprazole should be continued for up to 14 consecutive days during the initiation of the LAI to maintain therapeutic levels
- If adverse reactions occur a dose reduction to 300mg should be considered

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Request to Prescribe the Second Generation Antipsychotic LAI

Paliperidone and Aripiprazole

This form **must** be completed by a Consultant Psychiatrist and submitted to **both** the Chief Pharmacist and Deputy Medical Director for approval

ALL SECTIONS MUST BE FULLY COMPLETED

Patient name…… NHS Number……

Drug Requested

Diagnosis and Indications

Summary of history including capacity, insight, risk to self and others, urgent or imminent risks and any other pertinent issues that would qualify for in extremis (please add any additional information on a separate sheet)

Date June 2016, updated October 2018
Review Date October 2021

Previous medication history including details of efficacy, adverse drug reactions, concordance to treatment and consent (please add any additional information on a separate sheet).

Proposed Treatment plan – must include the rationale for the drug requested

Criteria for approval

CRITERIA	**Yes/No**
The patient fulfils the criteria as outlined in NICE guidance 178 for the prescribing of a LAI	
The patient has poor adherence to medication despite intervention to address this **OR** There are significant risk factors associated with non-adherence e.g. forensic issues, child protection, court orders, previous history of violence **OR** The patient is expressing a preference to be prescribed a depot formulation	
The patient has previously been prescribed a First Generation Antipsychotic (FGA) and has experienced intolerable side effects **OR** The patient is refusing to accept a FGA LAI **OR** The patient has not received a FGA LAI but the patient history shows that oral aripiprazole or oral risperidone have previously resulted in a positive therapeutic response (as demonstrated by improved symptom control, quality of life, occupational activity, reduction in inpatient admissions)	
The patient does not fulfil the criteria for clozapine as outlined in the NICE guidance 178 **OR** The patient is adamantly refusing to accept clozapine despite repeated attempts to address this **OR** Clozapine is contraindicated	
The prescribing will be within the licensed indications i.e. a diagnosis of schizophrenia **OR** The prescribing will be for other schizophreniform disorders e.g. schizoaffective disorder **OR** The prescribing is for bipolar disorder and there is poor adherence to oral antipsychotic treatment	
The patient has been prescribed the oral therapy as outlined in the SPC for each product	

Consultant: - ……..

Date:

Request Approved/ Not approved (rationale for non-approval will be stated here)

Deputy Medical Director: - ……

Date: -……

Chief Pharmacist: -……..

Date: -…….