Agenda item: 13 **Paper no: 13**

Title of Report:	**Locally Commissioned Service for Antipsychotic Drug Administration in Primary Care**	
Status:	**TO APPROVE**	
Committee:	**Primary Care Commissioning Committees in Common Part One**	**Date**: 13/09/2019
Venue:	Board Room, Third Floor, NHS G&W CCG, Dominion House, Woodbridge Road, Guildford, Surrey, GU1 4PU	

Presented by:	Donna Derby, Programme Director, NHS Surrey Heartlands CCGs	
Executive Lead sign Off:	Colin Thompson, Integrated Care Partnership Director, Surrey Downs	**Date**: 16/07/2019
Author(s):	Donna Derby, Programme Director, NHS Surrey Heartlands CCGs and Judi Mallalieu, NHS Surrey and Borders Partnership	

Governance:

Conflict of Interest: The Author considers:	**CONFLICT(S) NOTED** Name(s) of individuals with conflict: GP's in contract with Surrey Heartlands CCGs Mitigating Action(s): • Interest noted and participate in decision and discussion The formal decision to proceed with an LCS is taken at PCCC which mitigates the conflict.	✓
Previous Reporting: (relevant committees / forums this paper has previously been presented to)	None	
Freedom of Information: The Author considers:	Open – no exemption applies	✓

Executive Summary:

This LCS application is aligned to the successful transformation bid for monies to fund three pilot integrated mental health projects in three PCNs across Surrey Heartlands. GPimhs is the title

that the service is known by.

In order to fully complete the delivery of the services that support the GPimhs, an LCS is required to ensure that general practice is remunerated for the giving of the injections containing the long acting antipsychotic drugs. The full details of the service are contained in the attached paperwork which covers:

- The background to the pilot
- The service specification and
- An example of a shared care protocol. There will be a shared care protocol for each of the drugs covered under this LCS.

This LCS has now been considered by each Primary Care Operational Group (PCOG) in Surrey Heartlands and broadly welcomed but there was some additional information required namely:

- Needing the budget information for each PCOG as the delegated budgets are per CCG. The paper produced for PCOG set out a cost across all practices of circa £60k related to administration of the injections. This figure was based on anonymised data and therefore couldn't accurately cost each patient. [The antipsychotic drugs are variable in price and the frequency of receiving them also varies; this paper now updates that information per each PCOG].
- The other aspect regarding finance was clarity on a mechanism to transfer the drug costs from SaBP into the Primary Care prescribing budget; this will be worked through between the Medicines Management and Finance teams.
- The final issue was that it appears that the LCS should have been considered by the local Medicines Optimisation Groups,[MOGS]. This is being addressed through the late August/early September meetings in each CCG area, dependent on the scheduling of those monthly meetings.

It is recognized that it is unusual to bring a paper to PCCC without all aspects having been finalised, however as this LCS relates to a pilot service, waiting until the next PCCC in November will give very limited time for evaluation of this part of the pilot.

Given these circumstances the Chair of the PCCC has agreed for the PCCC to consider this paper, and then if acceptable to the membership, delegate final sign off under Chairman's action once the points highlighted above have been satisfactorily answered.

Implications:

What is the **health impact/ outcome** and is this in line with the **CCG's strategic objectives**?	• Achieving a sustainable system • Development of collaborative working • Developing Integrated Care at a local level • Primary Care development • Safe, effective care providing the best possible health and care outcomes and patient experience

What is the **financial/ resource** required?	• New investment from Delegated budget: NWS costs will be circa - £40,800 G&W costs will be circa - £32,800 SD's costs will be circa - £30,000
What **legislation, policy or other guidance** is relevant?	None
Is an **Equality Analysis** required?	No
Any **Patient and Public Engagement**/ consultation required?	Patients, through consultation with the Mental Health Stakeholders group, have been consulted as part of the development of the GP integrated mental health service (GPimhs)

Recommendation(s):

(1) To approve this LCS

Next Steps:

(1) To circulate the LCS to practices in Surrey Heartlands for applications to provide this service.

BACKGROUND

In early 2018, a Business Case was presented to the Surrey Heartlands Transformation Board to deliver a service to address the following identified issues:

- The substantial unmet need of patients in primary care presenting with mental health distress and that do not meet criteria for accessing IAPT services, and that absorbs significant capacity from GPs on non-clinical patient support. The unmet need of primary care patients not meeting access criteria for existing IAPT and secondary mental health care services. For some patients IAPT is not appropriate or what is needed, for example someone who is struggling with the breakdown of their marriage, or whose partner has been moved to a care home, or someone who may have longer term psychological issues that need to be worked through.
- The high level of patients in primary care not meeting the threshold for secondary care mental health services. There is a significant increase in GP practices of patients presenting with anxiety and depression linked to life circumstances, inability to cope, unemployment, debt and economic pressure, family pressures, changes in benefits system, and substance misuse.
- Those SMI patients who are in recovery and no longer require a secondary care service and deemed ready for transition to primary care. Patients in recovery from secondary care will benefit from integrated physical health and mental health support and guidance.
- Patients with physical health LTCs, MUS substance misuse presentations managed in GP practices that do not acknowledge the potential mental health component to their condition and do not access mental health support. SMI mortality rates are significantly higher than the population average. We need to provide an integrated physical and mental health offer for these patients with comorbid long term physical health conditions and patients presenting at primary care with mental health distress.
- Surrey Heartlands has a wealth of third sector community resources offering emotional and wellbeing support, and that can be better aligned and accessed as a core support offer for primary care mental health care service users.

The aim was to co-design and embed a new transformational model of integrated primary mental health care based on the emerging Primary Care Homes model, to reduce unmet need, improve access to existing services, better integrate physical and mental health, and reduce systems cost.

Current Situation

The bid was successful and just under £1m was released to develop a service in one PCN in each of the three CCG's; the service to initially run for 1 year. During the pilot phase the aim was to explore how the service could become sustainable for future years.

The pilot service is called GPimhs and is running in the PCN's that cover - North Guildford, in Guildford and Waverley CCG, Banstead in Surrey Downs CCG and CoCo in NWS CCG.

A team of staff has been recruited to each PCN managed by a clinical psychologist as the service lead. During the roll out of the service it's become clear that we need a mechanism to fund the delivery of the injections to the step down patients from secondary care into primary care. [The

costs of the drugs are not an issue as there is specific provision in the secondary care contract and monies can be transferred.] After discussion it is felt that the development of an LCS would be the best mechanism to fund the work in primary care.

It is recognised that whilst an LCS is open for all practices to take up, in this instance it may well be that only those practices in the PCN's engaged in the GPimhs pilot may take up the service. However, we do know that some practices already provide these long acting antipsychotic drug injections without payment and others may wish to do so as it benefits patients.

The intended specification is attached for discussion. This specification is based on a service already operational in Surrey Heath.

Proposed costings

The price attached to the delivery of the LCS is £19 per injection, based on the Surrey Heath LCS. Based on the first estimate of eligible patients supplied by SaBP it was estimated that the annual cost for the LCS would be circa £60k, however the table below sets out the most recent calculations drawn from both SaBP and Primary Care prescribing data.

	G&W CCG	NWS CCG	SD CCG	**TOTAL SURREY HEARTLANDS CCGs**
EPACT DATA				
Number of injections per year	2148	1726	1120	4994
Number of individuals	73	76	35	184
SAPB DATA				
Number of injections per year	751	820	1338	2909
Number of individuals	37	48	78	163
COMBINED DATA				
Number of injections per year	2899	2546	2458	7903
Number of individuals	110	124	113	347
Potential costs (based on £19 per injection)				
Estimate 1. Potential cost (assumes combined data number and that all	£55,081	£48,374	£46,702	£150,157

SABP patients transferred to primary care)				
Estimate 2. Potential costs (based on existing GP practice prescribing)	£40,812	£32,794	£21,280	£94,886

- In an audit carried out in NWS it seems that the practices already do most of the prescribing and SABP staff administer, so estimate 2 which is based on existing GP prescribing is likely to be more accurate.
- It appears that the situation in Guildford and Waverley is similar so again estimate 2.
- In Surrey Downs, the SABP data shows more injections given than prescribed by GPs so the assumption is that SABP are prescribing more for Surrey Downs patients than in the other 2 CCGs. The likely costs will therefore fall somewhere between estimate 1 and estimate 2 for this CCG.

The conclusion therefore is that:

NWS costs will be circa - £40,800

G&W costs will be circa - £32,800

SD's costs will be circa - £30,000

These figures should be used for budget purposes.

This pilot will give us information on the exact outcome and allow better estimates to be made for future planning.

There will also be a Shared Care protocol running alongside the LCS to ensure that there is clarity of the responsibilities of all parties and in particular the secondary care trust on the monitoring of the patient prior to offering the move to primary care.

Locally Commissioned Service LCSXXX – Antipsychotic drug administration in Primary Care

Service Specification

Service Ref:	Antipsychotic Drug Administration in Primary Care
Service:	Depot Injections
Commissioning Lead:	Surrey Heartlands Clinical Commissioning Group
Provider Lead:	SH CCG's
Start date:	TBC
Frequency of service review:	Annual / Bi-annual review of service
Date of last review undertaken:	Not applicable
End date:	TBC

1. Population Needs

National/local context and evidence base

Aim

- To increase primary care management of patients with stable but ongoing mental health needs.

Intended Outcome

- To reduce the number of patients attending routine outpatient attendances at specialist mental health trusts just to receive medication
- To provide greater choice and allow faster response to patient needs, without the need to attend a specialist centre
    - To Support the recovery model
    - To reduce stigma/encourage normalising treatment for people with mental health issues
    - Provide Care closer to home
    - Parity of esteem
    - Access to better physical health care

2. Outcomes

NHS Outcomes Framework Domains & Indictors

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	X
Domain 3	Helping people to recover from episodes or following injury	X
Domain 4	Ensuring people have a positive experience of care	X
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm	X

Locally defined outcomes

- Routine delivery of a current secondary care service. Will align with the LCS for physical Health checks.
- Destigmatising mental health

3. Scope

- **Aims & Objectives of service**

Background

- There is increasing evidence that long acting medication (LAI's) reduces the risk of relapse and increases time to rehospitalisation which supports the clinical strategy of early intervention to keep people out of hospital.
- Unlike oral antipsychotic medication there are no local prescribing agreements in place with all CCGs to support the prescribing and administration of LAIs in primary care. Therefore people prescribed LAIs have to come back to secondary care to receive their medication, whereas if they were prescribed the oral treatment form of the same drug for the same condition, they would get their medication from the GP, staying under the Care Programme Approach (CPA).
- This creates a number of challenges for the system including risk of stigma through lack of parity with other health conditions, reduced patient choice, reduced access to primary care and treatment further from home.

Aims & Objectives

To step down patients to primary care who are:

- In recovery and "stable" in secondary care mental health services
- That chose to receive ongoing care and support in primary care
- That would be well placed to alternatively receive recovery focused and integrated mental health care services in primary care, with seamless step-up and step-down as required.

Current formulations

Drug	Dose regime*
Aripiprazole	400 mg once monthly
Risperidone	25–50 mg every 2 weeks
Paliperidone palmitate	25–150 mg once monthly
Haloperidol decanoate	50–300 mg every 4 weeks
Fluphenazine decanoate	12.5–100 mg every 2 to 5 weeks
Flupentixol decanoate	50 mg every 4 weeks to 300 mg every 2 weeks
Pipotiazine palmitate	50–100 mg every 4 weeks
Zuclopenthixol decanoate	200–500 mg every 1 to 4 weeks

*Doses taken from relevant summary of product characteristics. The doses shown may not represent the full range that can be used and they do not imply therapeutic equivalence

To note: individual Shared Care Protocols have been developed for each of these formulations.

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Patient pathway

Eligibility – patients must meet the following criteria:

- stable on medication for last 6 months
- compliant with treatment plan and no DNAs in last 6 months

- no or stable psychopathology
- stable mood
- agree to transition to primary care
- on treatment intervals of at least two weeks
-
- Patient agrees to transition to primary care
- Transition supported by Care Plan which describes crisis and contingency plan, treatment plan (drug, frequency, dose, site and date of last injection) and physical health monitoring requirements
- GP to confirm happy to accept transition
- The GP will conduct a regular annual review of the person's physical health (using Bradford Physical Health Review template on EMIS to facilitate completion of the nine elements of the physical health check) If the GP has any concerns the case should be discussed with the local consultant psychiatrist and if required a further review of the person's mental health can be arranged.
- Initial probation period will be a minimum of 3 months
- Practice will have rapid access to CMHRS if concerns about patient

Patient medicines administered by Practice Nurse

- Nurse to receive suitable training (e.g. by SABP or GPimhs or Janssen)
- Suggest 15 minute appointment slot
- Template (EMIS) to be completed for each patient to include standard physical review plus brief mental health review (e.g. sign and symptoms of disease relapse)

- **Monitoring**

The practice will be required to complete the following:

- Compile a register of patients receiving anti-psychotic medication (LAI's)
- Have in place a system of recalling patients as required to meet their individual medication regime
- Have a system in place to monitor and action DNA's promptly and in collaboration with the patients carer where appropriate

- **Management of non-attendance**

- If person doesn't attend then practice nurse to call person and establish reason
- Rebook if agreeable within 7 days
- Ensure repeat LAI administered within 7 days
- If refusing or signs of relapse then escalate to local CMHRS
- If LAI not administered within 7 days of original date then escalate to local CMHRS (i.e. they have DNA'd twice)
- CMHRs to keep list of people transitioned to primary care
- The call to CMHRS to be actioned as an urgent referral by CMHRs and forwarded to rapid response team
- Injection due to be administered by CMHRS
- Assessment to be completed and outcome to be communicated to GP
- Outcome will either be that there is a reasonable explanation for DNA and to continue with primary care or the person needs to be reallocated a CMHRS care coordinator

Providers must have the following in place:

I. **A register.** Providers should be able to produce and maintain an up-to-date register of all patients transferred from secondary to primary care.

ii. **Call and recall.** There must be evidence of a robust, systematic and responsive recall system to ensure that patients receive their injection at the relevant time interval. In addition the Provider must have mechanisms in place to deal with non- attendees of appointments linking with secondary care for advice.

ii. **Health Professionals delivering the service**. Any health professionals involved in the care of patients should be appropriately trained.

iii. **Referral policies**. Where appropriate to refer patients promptly to the specialist service or liaise with them for advice

iv. **Record keeping**. To maintain adequate records of the service provided.

v. **Training.** Each provider must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so

- **Population covered including any acceptance & exclusion criteria & thresholds**

Patients who have consented to receiving their intra muscular antipsychotic medication in primary care and registered with any practice in a Surrey Heartlands CCG.

- **Interdependence with other service/providers**

Links with the Specialist Mental Health provider, SaBP and in particular the relevant CMHRS.

4. Applicable quality requirements & CQUIN Goals

Applicable Quality Requirements

Whilst rare all serious adverse drug reactions (ADRs) should be reported, even if the effect is well recognised. ADRs should be reported via the yellow care scheme
https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/

5. Location of service providers premises & Home visiting services

5.1 Providers premises

GP practice as stated on relevant Payment schedule pertaining to each Surrey Heartlands CCG

5.2 – Home visiting services

This locally commissioned service should be provided to all eligible patients as defined within the service specification. This includes any registered patients who are considered to be housebound and requiring treatment. It is unlikely that any housebound patients will meet the criteria for this LCS, but there may be an exception is the patient has other ongoing medical conditions that render them housebound.

The provider will receive the agreed LCS payment under the scheme and in addition, can claim the sum for attending a patient's home to provide treatment. Please refer to schedule 3 of the NHS Standard contract ref: NWSLCS2017/18 for the detail of all applicable payments. The "housebound payment" is in recognition of the additional resources required to deliver to this cohort of patients. Claims should be made via the quarterly claim form corresponding to the date range within which the original activity is delivered under the scheme.

6. Payments & Claims

6.1 Payment schedule

Payments will be made in line with those set out in the relevant payment schedule for all other LCS's available in the Surrey Heartlands CCG's.

6.2 Claiming method & timescale

All claims are to be made by the provider at the close of the quarter within which services have been delivered. Claims should be made via the individual quarterly claims form as provided by the lead commissioner.

Only claims submitted with the required evidence and within the applicable payment time from will be processed.
Claims received after the end of the financial year within which services were delivered will be processed for payment at the discretion of the lead commissioner.

6.3 EMIS Search & Report

As effective and accurate reporting relies on consistent read coding, a read code will be issued for activity relating to this LCS and guidelines are in development.

7. Sub-Contracting

7.1 Sub-Contracting

The Provider may wish to sub-contract the provision of certain elements or services commissioned under a Local Commissioned Services.
When deciding to appoint a sub-contractor the provider must:

- submit details of their accreditation process, which Commissioners will review and seek to agree in order to ensure the method is robust;
- Following any accreditation process undertaken by the Provider, the Commissioner will have the authority to veto the decision should the Commissioner be sufficiently concerned by the accreditation process and any material received as part of that process;
- The Commissioner may support the evaluation of any new sub-contracted party the Provider wishes to award a contract with.
- The commissioner will not be party to the sub contract arrangement and will therefore cannot be responsible any element of the commercial agreement.

The provider entering into the sub-contracting agreement retains responsibility for the delivery of the commissioned service(s) and is responsible for managing and overseeing the service provisions and ensuring that all requirements of the contract and service specification are being adhered to.

8. Post Payment Verification (PPV)

The commissioner has responsibility to ensure all services provide value for money and deliver safe quality care. The lead commissioner may request evidence to ensure payments made to providers under this agreement are in line with the contractual requirements outlined in the specification and valid as per the claim criteria and time frames specified.

The commissioner may request at any time, evidence to support any claims made or details of any sub-contracting arrangement, details must be provided within the requested timescale.

Where possible the lead commissioner will use tools available to validate expenditure and activity using available existing data i.e. audits and returns by providers and will aim to prevent repeat requests.

9. Termination period

Either party can terminate the service outlined in this specification by providing 3 months' notice in writing.

Termination of a single or multiple LCS service(s) does not affect all services listed within the NHS Standard contract ref: NWSLCS2017/18, unless specified. Individual service termination is required for each commissioned service and will need to be clearly specified.

At the end of the termination period the provider must make all activity claims as per the quarterly process as defined in section 8.2. Any payment applications for claims made after a service has expired will be reviewed by the lead commissioner on an individual basis and payment will be discretional.

NHS
North West Surrey
Clinical Commissioning Group

Locally Commissioned Service LCSXXX – Administration of Antipsychotic medications in Primary Care

Agreement:

Practice Name:	
Practice Address:	
Practice H Code:	

By signing and returning this document you AGREE to the terms and conditions of providing the Locally Commissioned Service LCS XXX – **Administration of Antipsychotic medications in Primary Care**
Signed by Partner of the practice:

Signature:	
Print Name:	
Date:	

Please return completed forms to:
Email: pc.contracts@nhs.net

(Electronic copies are acceptable but must be signed.)

Post: TBC

NHS
Surrey and Borders Partnership
NHS Foundation Trust

WORKING IN PARTNERSHIP WITH

NHS

Surrey Heath CCG

SHARED CARE Guideline – Amber Traffic Light Classification		
Name of medicine	Paliperidone *3 monthly* Long Acting Injection (Trevicta)	
Indication (including whether for adults and/or children)	Schizophrenia	
PCN policy statement reference (if applicable)		
Author(s): Simon Whitfield **Organisation(s):** SABP		
Version: 0.2	**MOG recommendation date:** April 2019	**Review date:** April 2020

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.
This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications.
The SCG must be used in conjunction with the PCN agreed core roles and responsibilities stated in annex A.
An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Circumstances when shared care is appropriate

Prescribing responsibility will only be transferred when the community consultant and the GP are in agreement that the patient's condition is stable or predictable, the patient is in agreement, and the patient is:

- stable on medication for last 12 months
- compliant with treatment plan and no DNAs in last 6 months
- no or stable psychopathology
- stable mood

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Consultant / Specialist

- Supply treatment for at least 12 months
- Agree with the patient that further injections will be administered by their GP
- Complete the request for shared care form and send to the GP, and ensure the form is returned by the GP with agreement
- Ensure the dose, frequency and site of last injection is clearly stated on the transfer request form
- Inform the GP that the patient has been on Paliperidone 3 *monthly* Long Acting Injection (Trevicta®) for at least 12 months
- Inform the GP of the results of baseline and subsequent tests including plasma glucose, plasma lipids, ECG and weight
- Inform the GP how often the patient will be reviewed by the CMHRS
- Send a copy of the Care plan which describes crisis and contingency plan
- Provide a rapid review should the GP request it
- Provide an annual review of the patient and provide the GP with an updated Care Plan

Primary Care Prescriber

- Ensure there is enough information to safely prescribe, administer and monitor treatment
- Provide ongoing prescriptions for Paliperidone 3 *monthly* Long Acting Injection (Trevicta®)

Practice Nurse

- Conduct pre administration assessment and record results/ action taken as per template
- The relapse indicators and early warning signs will be described in the crisis plan along with a recommended contingency plan
- Administer the injections and record as per template
- Ensure appointments are planned for regular 3 monthly injections and actively follow up any non-attendance
- Ensure the information gathered at each appointment is sent to the specialist for the annual review
- Discuss any concerns with GP who can contact CMHRS for advice

Date of assessment		**Name of Practice Nurse**	
Physical Health		**Result**	**Action required**
• BP			
• HR			
• Weight			
• BMI			
Any treatment side effects present?			
Mental Health (see Crisis plan)		**Response**	**Action Required (see crisis plan)**

Any relapse indicators or early warning signs present?		

Drug and dose administered	
Injection site	
Date of next appointment	

Management of non-attendance

- If the patient doesn't attend the planned appointment then the practice nurse will call patient and establish reason and rebook if agreeable within 7 days
- Ensure repeat LAI administered within 7 days
- If refusing or signs of relapse then escalate to local CMHRS
- If LAI not administered within 7 days of original date then escalate to local CMHRS (i.e. they have DNA'd with unsuccessful follow up)
- CMHRs to keep list of people transitioned to primary care
- The call to CMHRS to be actioned as an urgent referral by CMHRs and forwarded to rapid response team
- The injection due will then be administered by CMHRS
- Assessment to be completed and outcome to be communicated to GP
- Outcome will either be that there is a reasonable explanation for DNA and to continue with primary care or the person needs to be reallocated a care coordinator

Patient Relatives &/or Carers

- Report any adverse effect or warning symptoms to GP
- Inform the GP and specialist if intending to become pregnant
- To report to the GP if pregnant or breastfeeding
- Inform the GP and CMHRS of any changes in address or telephone contacts

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication

Long Acting Injections (LAIs) form an important part of managing patients who have either expressed a preference for the associated convenience in dosing or through intentional or unintentional non-concordance with treatment, which increases the risk of relapse and may increase the frequency of hospital admission. Although the use of LAIs does not guarantee good treatment adherence, for those who continue with LAIs, there may be some adherence advantage over oral antipsychotics which is demonstrated by a longer time to treatment discontinuation.[1]

Indication

There is established evidence for the use of antipsychotics in psychosis and schizophrenia[2] as well as in bipolar conditions[3]. First and second generation LAIs are considered to be equally effective[4], however there is considerable variation in the adverse effect profiles respectively.

Together with other factors such as patient preference, response and compliance to treatment with oral antipsychotics, medical and drug history often determine the choice of LAIs.

According to NICE Guidelines for Schizophrenia5, LAI antipsychotics should be offered to patients:

- 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.

Dosage and Administration

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance

Monitoring

Tests & Measurements (based on NICE Guidance for Psychosis & Schizophrenia CG178)	**Responsible clinician**
Baseline Monitoring • Fasting Glucose (or random if not possible) • HbA1C • Fasting Lipids (or random if not possible) • FBC • LFTs • U&Es including eGFR • Creatine Phosphokinase (CPK) • Prolactin • ECG - Recommended if: o Specified in SPC o Physical examination shows specific cardiovascular risk o Personal history of CVD o Admitted as inpatient • BP & Pulse • Weight & BMI • Waist Circumference	**Specialist**

Weekly for first 6 weeks • Weight & BMI	**Specialist**

At first 3 months of treatment • Fasting Glucose (or random if not possible) • HbA1C • Fasting Lipids (or random if not possible) • BP & Pulse • Weight & BMI	**Specialist**

Tests & Measurements (based on NICE Guidance for Psychosis & Schizophrenia CG178)	**Responsible clinician**

Annually • Fasting Glucose (or random if not possible) • HbA1C • Fasting Lipids (or random if not possible) • FBC • LFTs • U&Es including eGFR • Prolactin • ECG - Recommended if: o Specified in SPC o Physical examination shows specific cardiovascular risk o Personal history of CVD • BP & Pulse • Weight & BMI • Waist Circumference	**GP**

Note: Paliperidone is known to cause weight gain, dyslipidemia and glucose dysregulation. Paliperidone has a low effect on the cardiac QTc interval. However, patients with schizophrenia have a higher risk of sudden cardiac death than the general population. Thus the recommendation for annual ECG.

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Warning: Neuroleptic Malignant Syndrome, although very rare, is a medical emergency – signs and symptoms include hyperthermia, fever, sweating, muscle rigidity, autonomic instability, altered consciousness, confusion, fluctuating blood pressure, tachycardia, raised creatinine kinase.

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Practical issues
The maintenance dose can be administered once every 3 months. If necessary, the dose may be administered up to 14 days before or after the maintenance dose is due.

Missed dose

Missed doses	
If scheduled dose is missed and the time since last injection is	**Action**
> 3½ months up to 4 months	The injection should be administered as soon as possible and then resume the 3-monthly injection schedule.
4 months to 9 months	Use the recommended re-initiation regimen shown in the table below.

> 9 months	Re-initiate treatment with Paliperidone *Monthly Long Acting* Injection (Xeplion®) as described in the prescribing information for that product. Paliperidone *3 Monthly* Long Acting injection (Trevicta®) can then be resumed after the patient has been adequately treated

		with Paliperidone *monthly* Long Acting Injection (Xeplion®) preferably for four months or more.	
Recommended re-initiation regimen after missing 4 months to 9 months of Paliperidone *3 monthly Long Acting Injection* (Trevicta®)			
If the last dose of Paliperidone *3 monthly Long Acting Injection* (Trevicta®) was	**Administer Paliperidone monthly Long Acting Injection (Xeplion®), two doses one week apart (into deltoid muscle)**		**Then administer Paliperidone *3 monthly Long Acting Injection* (Trevicta®) (into deltoid[a] or gluteal muscle)**
	Day 1	**Day 8**	**1 month after day 8**
175 mg	50 mg	50 mg	175 mg
263 mg	75 mg	75 mg	263 mg
350 mg	100 mg	100 mg	350 mg
525 mg	100 mg	100 mg	525 mg
[a] See SPC also *Information intended for medical or healthcare professionals* for deltoid injection needle selection based on body weight.			

Rapid Response and Advice for the Primary Care

Monday-Friday between 9-5pm.

For rapid response or advice GPs can contact the Clinical Lead or Service Manager on 01276 454200

GPs can also email RXX.SHCMHRSAdmin@nhs.net for advice and support.

Please see the Crisis plan for relapse indicators and early warning signs and contingency plans.

Annex A: PCN agreed core roles and responsibilities for the shared care of medicines

Patients
To get the most out of your treatment it's important that you work together with your specialist. You must follow these guidelines to ensure your own safety, health and wellbeing. You should be able to decline shared care If after due consideration of the available options you decide it is not in your best interests. • You must make sure that you understand about your treatment • If you do not understand ask for more information from the person prescribing the medicine • Read the Patient Information Leaflet included with your medication. It will provide you with information about your medication • You must raise concerns about your treatment with the person prescribing the medicine • Talk to the specialist and come to an agreement of how the treatment should be provided to you • Give permission to have aspects of your care communicated to healthcare providers • Ensure that you are provided with contact details for support and help if required; both in and out of hours. • You must attend all appointments • You must keep a written list of all of the medicines you are taking • You must keep lists of any additional vitamins, minerals, or other dietary supplements • You must bring these lists with you each time you visit a healthcare provider or are admitted to a hospital • You must carry these lists on you in case of an emergency • You must not let anyone else take your medication. It is your responsibility to follow these guidelines. The guidelines are here for your safety, health and wellbeing. If you would like more information on your rights, roles and responsibilities in your healthcare please ask a NHS professional for information on the NHS constitution or visit, www.gov.uk/government/publications/the-nhs-constitution-for-england
Relatives and Carers
As a carer or relative (where it is not possible for the patient to make a decision about future treatment e.g. mental capacity, where possible you should be included in discussions about shared care. • To support the patient in fulfilling their roles and responsibilities as outlined above.
Consultant/ Specialist

Good Prescribing Guidelines

- Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required (RefGMC).
- Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required.
- Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the PCN with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care.
- Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the patient's CCG
- Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with your Formulary Pharmacist who will facilitate an update via the PCN

Before initiating treatment

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.
- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Undertake baseline monitoring and assessment.

Initiating and continuing treatment in secondary care

- Prescribe initial treatment and provide any associated training and counselling required.
- Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable or predictable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Post transfer of care

- Follow up and monitor the patient at appropriate intervals.
- Advise Primary Care Prescriber if treatment dose changes or treatment is discontinued
- Inform Primary Care Prescriber if patient does not attend planned follow-up

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the PCN as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.

- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation PCN representative who will facilitate an update via the PCN.

Annex B: Shared care agreement notification form for medicines and indications approved as amber on the Surrey PAD

For the attention of the Practice Manager

E-mail – Confirm both sender and recipient e-mail addresses are nhs.net before sending

To: [Recipient Name]
From: [Your Name]
Re: [Subject]
cc: [Name]

Date: [Click to select date]
Pages: [number of pages]

Name of medicine	Paliperidone 3 monthly Long Acting Injection (Trevicta 3 monthly injection)
Indication	Schizophrenia

Relevant patients GP available to action within 5 days (if not Trust needs to be informed on day of receipt of request)	**Yes/ No**
If GP is NOT available within 5 days, please communicate to the requesting specialist the date when the GP will be available	

Hospital/ Patient information		**Practice information**	
Consultant Making Request		GP Name:	
Consultant Speciality Details:		Practice:	
Patient Name:		I agree to undertake shared care:	
Patient NHS Number:		I do not agree to undertake shared care:	
Patient Hospital Number:		If NOT please give reasons:	
Patient DOB:		Signed:	
Drug Name/ Dose:		Date:	
Date and site of last injection:		Please return form to:	RXX.SHCMHRSAdmin@nhs.net
Next Injection Due:			
Care plan and crisis plan written and sent:			
Physical Health test results:		**Result of test:**	**Date of test:**
Fasting blood glucose or HbA1C			
Fasting lipids			
BP			
Pulse			

Wt and BMI		

Primary Care Prescriber should reply within 5 days of receipt of this form indicating participation (or not) in shared care of the patient