

**South East London Integrated Medicines Optimisation Committee
Formulary recommendation**

Reference	024
Intervention:	Paliperidone palmitate (Xeplion™, Trevicta™ and Byannli™) depot injection for the treatment of schizophrenia in adults (Paliperidone is an atypical antipsychotic. It is the active metabolite of risperidone and an antagonist of serotonin 5-HT and dopamine D2 receptors)
Date of Decision	February 2015, reviewed October 2023
Date of Issue:	March 2015, updated November 2015 & November 2023 to include the 6-monthly preparation Byannli™
Recommendation:	Amber 3 – Specialist (consultant) initiation and supply. GPs may be asked to take on prescribing under a full shared care agreement.
Further Information	<ul style="list-style-type: none"> • Where a depot antipsychotic injection is considered appropriate for adult patients with schizophrenia, haloperidol depot injection at low doses (75mg to 100mg a month) will be considered the depot of first choice. • Paliperidone depot injection is approved for use in line with its licensed indication – i.e. for the maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. • Three formulations of paliperidone palmitate are available on the SEL Joint Medicines Formulary: <ul style="list-style-type: none"> – Xeplion™ (1 monthly injection) – Trevicta™ (3 monthly injection) – Byannli™ (6 monthly injection) • Patients who are clinically stable on Xeplion™ may be switched to Trevicta™ 3-monthly injection. • Patients who are clinically stable on Xeplion™ or Trevicta™ may be switched to Byannli™ 6-monthly injection. • Patients switched to Trevicta™ or Byannli™ will be switched by the specialist mental health service. • Paliperidone palmitate is available in pre-filled syringes and is administered via the intramuscular route. The Byannli™ preparation must be administered in the gluteal muscle only. The product does not require reconstitution or refrigeration and does not require post-administration observation of the patient. • Patients must be stable for 12 months following initiation after which transfer to primary care can be considered under the shared care arrangement. • Written support material will be provided to the patient to aid decision making around choice of antipsychotic agent. • Individual boroughs will need to discuss implementation of this recommendation at a local level. In particular: <ul style="list-style-type: none"> – its impact on pathways for commissioning mental health services and – staff education/training to enable it to be prescribed and administered safely in the community
Shared Care/ Transfer of care required:	Yes
Cost Impact for agreed patient group	<ul style="list-style-type: none"> • Figures provided by SLAM (the main current user) suggest around 450 patients are currently prescribed this drug within the Trust. The numbers of patients at Oxleas are negligible. • If a third of these patients are successfully transferred to primary care, this will have a cost implication of approximately £800K. The majority of this cost is anticipated to be associated with 3 SEL boroughs who commission services from SLAM (Lambeth, Lewisham and Southwark). SEL ICB boroughs should

	<p>ensure that suitable processes are agreed and in place to manage funding flows for these patients e.g. through contractual agreements.</p> <ul style="list-style-type: none"> The evidence evaluation considered by the Committee states that 20 patients per 100,000 population may be eligible for treatment with paliperidone depot injection. If 50% of these actually received the drug, the annual cost would be £22,000 to £47,000 per 100,000 population. This excludes any service delivery related costs.
Usage Monitoring & Impact Assessment	<p>Acute Trusts:</p> <ul style="list-style-type: none"> Monitor and submit usage data on request to the Committee. Ensure shared care guideline is provided and adhered to, provide audit data and data on outcomes upon request for reporting back to the Committee. <p>SEL Borough Medicines Teams:</p> <ul style="list-style-type: none"> Monitor exception reports from GPs if inappropriate transfer of prescribing to primary care is requested
Evidence reviewed	<p>References (from London Medicines Evaluation Network review)</p> <ol style="list-style-type: none"> NICE clinical guideline on the management of schizophrenia (CG 178) February 2014 Second-generation long-acting injectable antipsychotic agents: an overview. DTB 2012; 50 (9): 102-105 Carter N J et al. Extended-Release Intramuscular Paliperidone Palmitate A Review of its Use in the Treatment of Schizophrenia. Drugs 2012; 72 (8): 1137-1160 Paliperidone palmitate (XEPLION) SPC (date of revision = 3 December 2013) SMC summary on paliperidone palmitate (7 October 2011) SMC summary on olanzapine embonate (9 August 2010) SMC summary on aripiprazole prolonged release suspension for injection (Abilify Maintena®) (12 May 2014) AWMSG summary on paliperidone palmitate (Xeplion®) 9 November 2012 AWMSG summary on aripiprazole (Abilify Maintena®) (13 AWMSG summary on olanzapine depot (ZypAdhera®) (17 November 2010) Olanzapine embonate (ZypAdhera®) SPC (Date of revision = 25 April 2014) Risperidone long-acting injection SPC (Risperdal Consta®) (Date of revision = November 2013) Nussbaum A M. Paliperidone palmitate for schizophrenia. Cochrane Database of Systematic Reviews 2012, Issue 6. Art. No.: CD008296. DOI: 10.1002/14651858.CD008296.pub2. (12 July 2011) McEvoy J P et al. Effectiveness of paliperidone palmitate vs haloperidol decanoate for maintenance treatment of schizophrenia. A randomised clinical trial. JAMA 2014; 311 (19): 1978-1986 Li H et al. A comparative study of paliperidone palmitate and risperidone long-acting injectable therapy in schizophrenia. Progress in Neuro-Psychopharmacology & Biological Psychiatry 2011; 35: 1002-1008 EMA EPAR on paliperidone palmitate (Xeplion) Doc. Ref.: EMA/60983/2011 – published 2011 Maudsley Prescribing Guidelines in Psychiatry 11th edition British National Formulary 68 (September 2014 to March 2015) NICE evidence summary on lurasidone 23 September 2014 Taylor D et al. Long-acting paliperidone palmitate – interim results of an observational study of its effect on hospitalization. International Clinical Psychopharmacology 2014, 29:229–234 Leucht S et al. Second-generation versus first-generation antipsychotic drugs for schizophrenia: a meta-analysis. Lancet 2009; 373: 31–41 Trevicta Summary of Product Characteristics. Available here [Accessed 03/11/2023] Byanli Summary of Product Characteristics. Available here [Accessed 03/11/2023]

NOTES:

- SEL IMOC recommendations and minutes are available publicly via the [website](#).
- This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
- Not to be used for commercial or marketing purposes. Strictly for use within the NHS**