

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

Reference	092
Intervention:	Levonorgestrel 52mg (20 micrograms/24 hours) Intrauterine Delivery System (Levosert[®]) for the treatment of heavy menstrual bleeding and contraception and Levonorgestrel 19.5 mg Intrauterine Delivery System (Kyleena[®]) for contraception
Date of Decision:	July 2018. Updated March 2022 to reflect updated licensing for Levosert[®]. Updated October 2024 to reflect updated licensing for Levosert[®]
Date of Issue:	August 2018. Re-issued March 2022 to reflect updated licensing for Levosert[®]. Re-issued October 2024.
Recommendation:	GREEN – can be prescribed within agreed criteria for use in primary or secondary care
Further Information	<ul style="list-style-type: none"> Levonorgestrel 52mg (20 micrograms/24 hours) Intrauterine Delivery (IUD) System (Levosert[®]) is accepted as an option in South East London for the treatment of heavy menstrual bleeding and as an option for long acting reversible contraception. From August 2024, the licensing for Levosert[®] has been updated to reflect its effective use as contraception for up to eight years. Levonorgestrel 19.5 mg IUD System (Kyleena[®]) is accepted as an option in South East London for long acting reversible contraception. It is effective for five years of use. Levosert[®] will be an alternative to Mirena[®] IUD System (levonorgestrel 52 mg [20 micrograms / 24 hours – effective for 8 years]) as hormonal treatment of heavy menstrual bleeding. Levosert[®] and Kyleena[®] will be alternatives to Mirena[®] and Jaydess[®] IUD System (levonorgestrel 13.5 mg – effective for 3 years) for long acting reversible contraception. Levosert[®] is not licensed for use in menopausal women or women who require hormone replacement therapy (HRT), Mirena[®] is licensed in this patient cohort and should be considered. The choice of IUD system for both indications will depend on patient choice, clinical parameters, licensing and local availability. As there are differing methods of insertion, healthcare professionals should be trained to insert the devices available locally, and it should be prescribed by brand to ensure the correct device is used.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	<ul style="list-style-type: none"> Both Kyleena[®] and Levosert[®] are available at a lower cost per year of treatment than Mirena[®] and Jaydess[®], and therefore introduction of these new agents is likely to be cost saving.
Usage Monitoring & Impact Assessment	Acute Trusts
	<ul style="list-style-type: none"> Monitor and submit usage and audit data on request to the SEL IMOC. SEL Borough Medicines Optimisation Teams: <ul style="list-style-type: none"> Monitor primary care prescribing data.

Evidence reviewed	References (from evidence evaluation)
	<ol style="list-style-type: none"> 1. Levosert, Summary of Product Characteristics. Available online at: https://www.medicines.org.uk/emc/product/1789 (accessed 03/03/2022) 2. Kyleena; Summary of Product Characteristics. Available online at: https://www.medicines.org.uk/emc/product/769 (accessed 05/06/2018) 3. Long Acting Reversible Contraception. National Institute for Health and Care Excellence CG30 (updated 2014). Available online at: https://www.nice.org.uk/guidance/cg30/ (accessed 05/06/2018) 4. Heavy Menstrual Bleeding: Assessment and management. National Institute for Health and care Excellence NG88. Available online at: https://www.nice.org.uk/guidance/ng88/ (accessed 05/06/2018) 5. Mirena: Summary of Product Characteristics. Available online at: https://www.medicines.org.uk/emc/product/1132 (accessed 14/06/2018) 6. Kyleena – another levonorgestrel IUS. Drug and Therapeutics Bulletin 2018 56 (2) p18-20 7. Levosert 20 microgram/ 24 hours intrauterine delivery system. Public Assessment Report. MHRA 8. Mawet M, Nollevaux F, Nizet D et al. Impact of a new levonorgestrel intrauterine system, Levosert®, on heavy menstrual bleeding: results of a one-year randomised controlled trial. European Journal of Contraception and Reproductive Health Care 2014 9. Eisenberg D, Schreiber C, Turok D et al. Three-year efficacy and safety of a new 52-mg levonorgestrel-releasing intrauterine system. Contraception 2015 92 (1) p10-16 10. A Study of a Levonorgestrel-Releasing Intrauterine System for Long-Term, Reversible Contraception. NCT00995150. Protocol available online at: https://clinicaltrials.gov/ct2/show/NCT00995150 (accessed 14/06/2018) 11. Nelson A, Apter D, Hauck B et al. Two low-dose levonorgestrel intrauterine contraceptive systems, a randomised controlled trial. Obstetrics and Gynaecology 2013 122 (6) p1205-1213 12. Gemzell-Danielsson K, Apter D, Dermout S et al. Evaluation of a new, low dose levonorgestrel intrauterine contraceptive system over 5 years of use. European Journal of Obstetrics and Gynaecology and Reproductive Biology 2017 210 p22-28 13. Differentiation of Kyleena, Mirena and Jaydess. Kyleena Education Pack. Available online at: https://www.medicines.org.uk/emc/rmm/1018/Document (accessed 01/07/2018) 14. British National Formulary. Available online at: https://www.medicinescomplete.com/#/content/bnf/_944861997?hspl=Levonorgestrel (accessed 01/07/2018) 15. Levonorgestrel (Levosert) 20 microgram/24 hour intrauterine delivery system 1058/15. Scottish Medicines Consortium 2015. 16. Levonorgestrel 19.5 mg intrauterine delivery system (Kyleena) 1299/18. Scottish Medicines Consortium 2018. 17. Levosert, Summary of Product Characteristics. Available online at: https://www.medicines.org.uk/emc/product/1789 (accessed 04/10/2024) 18. Long Acting Reversible Contraception. National Institute for Health and Care Excellence CG30 (updated 2019). Available online at: https://www.nice.org.uk/guidance/cg30/ (accessed 04/10/2024)

NOTES:

- a) SEL IMOC recommendations and minutes are available publicly via the [website](#).
- b) 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.
- c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**