Prescribing Clinical Network

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath), Crawley CCG and Horsham & Mid-Sussex CCG

Title of paper:	Oxycodone - A review of available oral oxycodone products to determine the product of choice when oxycodone prescribing is required						
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Executive Summary:

The aim of this review is to compare oxycodone MR and IR tablets/capsules available to determine the product of choice to recommend in primary care to enable patients to access these drugs in a safe and cost-effective way. Ideally, this should be in line with local provider choices.

Oxycontin MR tablets and Oxynorm IR capsules are the originator products with various generic versions now available. The Care Quality Commission (CQC) has issued guidance recommending that "where possible prescribe by brand to reduce confusion". Current prescribing patterns in primary care indicate that there is a significant amount of generic prescribing which may lead to patient safety risks as highlighted by CQC.

In terms of safety oxycodone preparations should be prescribed by brand name to avoid confusion between formulations with different durations of action.

This paper summarises a number of factors that will influence local choices and makes recommendations on suitable preferred choices.

Summary:

PCN is asked to:

1) Endorse the recommendations for local adaptation.

Accompanying papers (please list):

None

Author's Potential Conflicts of Interest: None

Oxycodone - A review of available oral oxycodone products to determine the product of choice when oxycodone prescribing is required

1. Purpose of the Review

The aim of this review is to compare oxycodone MR and IR tablets/capsules available to determine the product of choice to recommend in primary care to enable patients to access these drugs in a safe and cost-effective way. Ideally, this should be in line with local provider choices.

Oxycontin MR tablets and Oxynorm IR capsules are the originator products with various generic versions now available. The Care Quality Commission (CQC) has issued guidance recommending that "where possible prescribe by brand to reduce confusion". Current prescribing patterns in primary care indicate that there is a significant amount of generic prescribing which may lead to patient safety risks as highlighted by CQC.

In terms of safety oxycodone preparations should be prescribed by brand name to avoid confusion between formulations with different durations of action.

2. Rationale for the use of branded oxycodone products

Indication

Oxycodone is a strong opioid indicated for post-operative pain, severe pain, and moderate to severe pain in palliative care¹ and is at step 3 of the WHO analgesic ladder. Oxycodone should only be used as a second line strong opioid, if morphine is not suitable or not tolerated². Oxycodone has an efficacy and side-effect profile similar to that of morphine. There are no advantages in using oxycodone as first-line for moderate to severe pain, oxycodone is an alternative for the small number of patients who develop intolerable adverse effects with oral morphine or who do not respond to morphine³.

Safety

A large number of patient safety incidents involving oral oxycodone medicines have been reported to the National Reporting and Learning System (NRLS). The Care Quality Commission guidance on the *Safer use of controlled drugs—preventing harm from oral oxycodone medicines*, which was co-developed with NHS England², states that

— 'where possible prescribe by brand to reduce confusion' in order to reduce the chance of an immediate-release preparation inadvertently being prescribed or administered in place of a modified-release preparation. There are significant risks of overdose when a fast acting product of short duration is used in error for the slow acting, longer duration products.

3. Dose

Modified release preparations

In general, the initial dose for opioid naïve patients for modified release preparations is 10 mg oxycodone hydrochloride given at intervals of 12 hours. Some patients may benefit from a starting dose of 5 mg to minimise the incidence of side effects. Patients already receiving opioids may start treatment with higher dosages taking into account their experience with former opioid therapies.

Immediate release preparations

In general, the initial dose for opioid naïve patients for immediate release capsules is 5 mg oxycodone hydrochloride given at intervals of 6 hours. Patients already receiving opioids may start treatment with higher doses taking into account their experience with former opioid therapies.

4. Comparison of pharmacokinetic data of products

The branded generic oxycodone medicines authorised by MHRA are comparable in quality and bioequivalent to Oxycontin and Oxynorm. As they are generic medicines, studies in patients are limited to tests to determine that they are bioequivalent to the reference medicine, Oxycontin and Oxynorm.

5. Supply chain

Information regarding the availability through pharmaceutical wholesalers of branded oxycodone products is shown in appendix A, figure 1.

All products are available through Alliance Healthcare and AAH, although Zomestine MR tablets are only available from AAH through a system called TPOS (third party ordering system). Other supplying wholesalers for products include Phoenix Healthcare, Mawdsleys, Sangers, Norchem/Lexo, Maltbys, Sigma, DE and Lexon⁶.

Longtec/Shortec is manufactured at the same site as Oxycontin/ Oxynorm and obtained from the same wholesalers⁶.

6. Strength availability and appearance of oxycodone preparations

Full details of formulations available and appearance of products is shown in Appendix B, tables 12 and 13.

Oxycontin and Longtec are available in all strengths with Abtard, Oxeltra, and Reltebon supplied in all strengths apart from 120mg; however this strength is not commonly used. Formulations unavailable for the remaining oxycodone products can be made up from other existing strengths, although careful communication to the patient regarding a combination of oxycodone strengths prescribed needs to be considered if switching to this occurs.

In terms of colour and size most products are similar apart from the 5mg Oxylan MR tabs and all strengths of Zomestine MR tabs. Zomestine MR 20mg, 40mg and 80mg are slightly larger in size than the others. Oxycontin MR and Longtec MR are manufactured at the same site, to the same formula and utilising the same process^{6.7}. Longtec MR is therefore identical in appearance to Oxycontin MR but marketed as a generic.

All oxycodone IR capsules are similar apart from the colour of 5mg Lynlor capsules. Oxynorm and Shortec are manufactured at the same site and are identical in appearance but Shortec is marketed as a generic⁶.

7. Table 1: Current preferred choices in acute trusts⁸

Trust	Modified release tabs	Standard release caps
ASPH	Oxycontin MR tabs	Oxynorm caps
ESHUT	Oxylan MR tabs	Lynlor caps
FPH	Oxycontin/Longtec MR tabs	Oxynorm caps
RSCH	Oxylan MR tabs	Oxynorm caps
SASH	Oxycontin MR tabs	Oxynorm caps
Kingston	Oxylan MR tabs	Lynlor caps

8. Current prescribing patterns in primary care

The following tables indicate data based on primary care FP10 prescriptions from Dec 15 to May 16 for each CCG and includes all strengths of each oxycodone product. The top 2 products prescribed are highlighted.

The pattern of prescribing shows relatively widespread prescribing of oxycodone MR / oxycodone IR written generically and Oxycontin MR tabs / Oxynorm caps across the 5 CCG's. The product supplied against generic prescriptions is dependent on the providing pharmacy and in terms of safety this is not recommended. North West Surrey CCG also has a high usage of Reltebon MR tabs / Lynlor caps for certain strengths. Nationally, Longtec MR tabs / Shortec and generic oxycodone MR / oxycodone IR are the most commonly prescribed products. The relatively high use of Longtec nationally indicates that many CCGs around the country have already made a change.

Table 2: Oxycodone MR tabs prescribing patterns - by brand

	Abtard	Carexil	Longtec	Oxeltra	Oxycodone	OxyContin	Oxylan	Reltebon
National	0.2%	0.0%	<mark>42.2%</mark>	0.0%	<mark>38.5%</mark>	15.7%	0.1%	3.2%
NW Surrey	0.0%	0.2%	0.0%	0.0%	<mark>55.8%</mark>	14.6%	0.3%	<mark>29.2%</mark>
East Surrey	0.0%	0.0%	1.7%	0.0%	<mark>58.1%</mark>	<mark>40.2%</mark>	0.0%	0.0%
Guildford & Waverley	0.0%	0.0%	0.0%	0.1%	<mark>65.8%</mark>	<mark>30.6%</mark>	0.0%	3.5%
Surrey Downs	0.0%	0.0%	0.0%	0.0%	<mark>68.6%</mark>	<mark>30.8%</mark>	0.0%	0.5%
Surrey Heath	0.0%	0.0%	0.0%	0.0%	<mark>69.9%</mark>	<mark>30.1%</mark>	0.0%	0.0%

Table 3: Oxycodone MR tabs prescribing patterns – by strength

	5mg M/R	10mg M/R	15mg M/R	20mg M/R	30mg M/R	40mg M/R	60mg M/R	80mg M/R	120mg M/R
National	11.3%	31.0%	2.8%	25.0%	6.3%	13.3%	3.3%	6.1%	0.9%
NW Surrey	14.4%	32.9%	5.4%	23.3%	5.3%	10.2%	3.1%	5.2%	0.0%
East Surrey	9.1%	37.1%	1.8%	22.9%	7.8%	12.9%	2.4%	6.0%	0.0%
Guildford & Waverley	12.1%	26.5%	2.6%	27.8%	9.0%	13.2%	4.7%	3.8%	0.4%
Surrey Downs	13.3%	24.6%	4.8%	31.4%	11.9%	7.8%	2.9%	3.1%	0.1%
Surrey Heath	10.0%	29.6%	1.3%	28.4%	4.2%	10.9%	1.9%	11.7%	2.1%

Table 4: Oxycodone IR caps prescribing patterns – by brand

	Lynlor	Oxycodone	OxyNorm	Shortec
National	5.8%	<mark>43.7%</mark>	20.8%	<mark>29.7%</mark>
NW Surrey	<mark>33.7%</mark>	<mark>50.6%</mark>	15.7%	0.0%
East Surrey	0.0%	<mark>62.5%</mark>	<mark>37.5%</mark>	0.0%
Guildford & Waverley	8.8%	<mark>65.3%</mark>	<mark>25.9%</mark>	0.0%
Surrey Downs	1.8%	<mark>63.4%</mark>	<mark>33.6%</mark>	1.1%
Surrey Heath	0.0%	<mark>61.2%</mark>	<mark>38.8%</mark>	0.0%

Table 5: Oxycodone IR caps prescribing patterns – by strength

	5mg	10mg	20mg
National	42.1%	36.3%	21.7%
NW Surrey	50.2%	36.9%	12.9%
East Surrey	34.4%	39.6%	26.0%
Guildford & Waverley	41.0%	42.7%	16.4%
Surrey Downs	29.4%	48.7%	21.8%
Surrey Heath	44.6%	35.9%	19.5%

9. Cost comparison

Table 6: Cost of available Oxycodone MR tabs^{6,9,10,11}

Strength	Abtard MR (56 tabs)	Carexil MR (56 tabs)	Longtec MR (56 tabs)	Oxeltra MR (56 tabs)	Oxycontin MR (56 tabs)	Oxylan MR (56 tabs)	Reltebon MR (56 tabs)	Zomestine MR (56 tabs)	Oxycodone HCL MR (56 tabs)
5mg	12.52	12.52	12.52	27.18	25.04	25	12.52	10.02	25.04
10mg	12.52	12.51	12.52	27.19	25.04	24.99	12.52	10.02	25.04
15mg	19.06		19.06	41.39	38.12		19.06		38.12
20mg	25.04	25.04	25.04	54.37	50.08	49.98	25.04	20.03	50.08
30mg	38.11		38.11	82.76	76.23		38.11		76.23
40mg	50.09	60.11	50.09	108.78	100.19	99.98	50.09	40.08	100.19
60mg	76.24		76.24	165.56	152.49		76.24		152.49
80mg	100.19	120.23	100.19	217.57	200.39	199.97	100.19	80.16	200.39
120mg			152.51		305.02				305.02

Prices illustrated in table 6 are based on a supply of 56 tablets which assumes 1 month supply.

Table 7: Potential annual savings of Oxycodone MR tabs⁶

	Abtard MR (56 tabs)	Carexil MR (56 tabs)	Longtec MR (56 tabs)	Oxeltra MR (56 tabs)	Oxycontin MR (56 tabs)	Oxylan MR (56 tabs)	Reltebon MR (56 tabs)	Zomestine MR (56 tabs)
NW Surrey	£39,315	£22,089	£39,315	-£34,903	-£24,042	-£21,450	£39,315	£38,892
East Surrey	£41,483	£30,489	£41,483	-£7,464	-£300	£105	£41,483	£40,923
Guildford & Waverley	£46,569	£31,062	£47,484	-£9,703	-£1,469	-£992	£46,569	£41,598
Surrey Downs	£50,223	£33,646	£50,528	-£9,141	-£455	£344	£50,223	£43,532
Surrey Heath	£27,793	£22,055	£30,538	-£4,765	£0	£283	£27,793	£29,986

Cost savings calculated are based on data from prescriptions over a 6 month period (Dec 15 to May 16) for the 5 CCG's and extrapolated to provide an annual cost saving. The figure details the saving compared to current costs if that product was prescribed for all prescriptions (where a strength is unavailable the originator brand price has been used).

Prescribing oxycodone MR tabs as Abtard MR, Longtec MR, Reltebon MR would release the most amount of savings. The small gain in some CCGs when prescribing Longtec MR relates to the 120mg strength which is not available with the other products.

Table 8: Cost of Oxycodone IR caps^{9,10}

Strength	Lynlor	Oxynorm	Shortec	Oxycodone HCL
5mg	6.86	11.43	6.86	11.43
10mg	13.72	22.86	13.72	22.86
20mg	27.43	45.71	27.43	45.71

Prices illustrated in table 8 are based on a supply of 56 capsules.

Table 9: Potential savings of Oxycodone IR caps

	Lynlor	Oxynorm	Shortec	Oxycodone HCL
NW Surrey	£6,274	-£4,040	£6,274	-£4,040
East Surrey	£12,221	£0	£12,221	£0
Guildford &	£6,957	-£813	£6,957	-£813
Waverley				
Surrey Downs	£15,328	-£603	£15,328	-£603
Surrey Heath	£4,929	£0	£4,929	£0

Cost savings calculated are based on data from prescriptions over a 6 month period (Dec 15 to May 16) for the 5 CCG's and extrapolated to provide an annual cost saving. The figure details the saving if that product was prescribed for all prescriptions. Prescribing oxycodone capsules as Lynlor or Shortec would release the most amount of savings.

10. Oxycodone product comparison table and scoring

Oxycodone MR tabs and oxycodone capsules are compared against various criteria in table 10 and 11. Scoring is 1 to 3 with 3 being more preferable. It is acknowledged that this is a subjective view of the author to assist as a guide.

All products are bioequivalent so are compared in terms of cost, supply chain (wholesalers the product is available through), the formulations available and appearance. It is important to consider the strengths available as if a patient is switched to a product not available in their current dose they will need to take a combination of tabs which may induce some confusion. Most prescriptions within the CCG's are for the originator products or written generically so in terms of patient acceptability the appearance (colour and size) of the formulation is compared against Oxycontin and Oxynorm. Patients may be more reassured if their new product is similar to their existing one.

Current prescribing in acute trusts, CCG's and nationally was reviewed and taken into account but not scored as these are subject to change according to local guidelines.

Longtec MR and Reltebon are the top 2 scoring products for the MR preparations and Lynlor and Shortec for oxycodone IR caps.

Table 10 - Oxycodone MR tabs comparison table

	Cost	Supply chain	Strength availability	Appearance	Score
Abtard MR	3	2	3	2	10
Carexil MR	2	2	1	2	7
Longtec MR	3	3	3	3	12
Oxeltra MR	1	3	3	2	9
Oxycontin MR	1	3	3	3	10
Oxylan MR	1	3	1	1	6
Reltebon MR	3	3	3	2	11
Zomestine MR	3	2	1	1	7

Table 11 - Oxycodone capsules comparison table

	Cost	Supply chain	Strength availability	Appearance	Score
Lynlor	3	3	3	2	11
Oxynorm	1	3	3	3	10
Shortec	3	3	3	3	12

11. Risks

Potential concerns of recommending a particular branded generic is that selling prices may vary, with one generic company having the lowest list prices one month but then the following month, another company then reduces their list prices or the company increases their prices. Another risk with the use of branded generics has been ensuring that supplies of the drug do not run out due to sudden increases in use. This would be particularly problematic with controlled drugs with their additional requirements to comply with the relevant prescriptions requirements. Prescribing by brand limits the product dispensed so any supply problems would impact patients, GP surgeries and community pharmacies.

Switching patients to a particular brand of oxycodone may cause confusion for the patient. To avoid any duplication or potential harm to the patient careful communication of the switch is essential with advice to use up old medicines first and warning of a change in packaging and slight differences in size/colour of formulation.

Information regarding the choice of product in acute trusts may change dependant on NHS contracts so patients may be supplied a different brand to what primary care are using which may cause confusion for the patient and additional workload for the surgery to switch the patient.

Consideration should be given to space for stock within controlled drugs cupboards in community pharmacies. Local community pharmacies should be notified in advance of the switch, and choice of low cost brand, to enable effective management of stock.

12. Conclusion

Brand prescribing of oxycodone products is recommended due to safety concerns. After considering the different options, Longtec MR and Reltebon MR are the MR preparations of choice and Lynlor and Shortec are the IR formulations of choice in primary care.

Using Longtec and Reltebon as branded generics could release savings of over £200,000 per annum across the 5 CCG's with approximately £45,000 per annum savings using Lynlor and Shortec.

Patients should be switched to the above products following the oxycodone switch implementation plan to mitigate risks.

13. References

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Appendix A

Figure 1: Supply chain of oxycodone preparations

Products	Wholesalers
Abtard MR tabs	The wholesalers supplying Abtard are Alliance Healthcare and AAH
Carexil MR tabs	All major wholesalers stock this product (for example, Alliance and AAH)
Longtec MR tabs and Shortec caps	The wholesalers are Alliance Healthcare, Phoenix Healthcare and AAH
Oxeltra MR tabs	The main wholesalers are:- AAH Pharm / Alliance / Mawdsleys and Phoenix
Oxycontin MR tabs and Oxynorm Caps	The wholesalers are Alliance Healthcare, Phoenix Healthcare and AAH
Oxylan MR tabs	Chanelle Medical U.K. Limited usually carries between 6 months to 1 year's amount of stock. From their stock they supply the usual wholesalers both full line (Alliance, Phoenix, Mawdsleys, etc.) and short line (Sigma, DE, Lexon, etc.). Any wholesaler who requires the stock can freely purchase from Chanelle U.K. Limited
Reltebon MR tabs and Lynlor caps	Wholesaler stockists are AAH, Alliance, Phoenix, Sangers, Norchem/Lexo, Mawdsleys, and Maltbys. The active pharmaceutical ingredient (API) is sourced in the UK and manufactured at their UK plant based in Barnstaple, Devon
Zomestine MR tabs	The wholesaler is Alliance Healthcare (Distribution) Limited (AHDL). If pharmacies still wish to order through Celesio/AAH, they can still do so through a system called TPOS (third party ordering system) and they will still receive the same delivery service

<u>APPENDIX B</u>

Table 12: Comparison of available formulations and size of oxycodone MR tabs^{4,6}

Strength	Abtard MR tablets	Carexil MR tablets	Longtec MR tablets	Oxeltra MR tabs	Oxycontin MR tablets	Oxylan MR tablets	Reltebon MR tablets	Zomestine MR tablets
5mg	Blue, round, biconvex, 7mm in diameter, 2 years shelf life	Blue, round, biconvex, 5.3mm – 5.9mm, 5 years shelf life	Light blue, round, approx. 7 mm diameter, 3 years shelf life	Blue, round, biconvex, 7mm, 2 years shelf life	Light blue, round, approx. 7 mm diameter, 3 years shelf life	Light grey, round and biconvex, 5.1mm in diameter, shelf life 5 years	Blue, round, biconvex, 7 mm in diameter, shelf life 2 years	White to off-white, 5.2 – 5.3 mm round, shelf life 3 years
10mg	White, round, biconvex, 9mm in diameter, 2 years shelf life	White, round, biconvex, 6.8mm –7.4mm, 5 years shelf life	White, round, approx. 7 mm diameter, 3 years shelf life	White, round, biconvex, 9mm, 2 years shelf life	White, round, approx. 7 mm diameter, 3 years shelf life	White, round and biconvex, Diameter: 7.1 mm, shelf life 5 years	White, round, biconvex, 9 mm in diameter, shelf life 2 years	Pink, oblong, 10.3 – 10.4 mm in length, biconvex, shelf life 3 years
15mg	Grey, round, biconvex, 9mm in diameter, 2 years shelf life	Not available	Grey, round, approx. 8 mm diameter, 3 years shelf life	Grey, round, biconvex, 9mm, 2 years shelf life	Grey, round, approx. 8 mm diameter, 3 years shelf life	Not available	Grey, round, biconvex, 9 mm in diameter, shelf life 2 years	Not available
20mg	Pink, round, biconvex, 7mm in diameter, 2 years shelf life	Pink, round, biconvex, 6.8mm– 7.4mm, 5 years shelf life	Pink, round, approx. 7 mm diameter, 3 years shelf life	Pink, round, biconvex, 7mm, 2 years shelf life	Pink, round, approx. 7 mm diameter, 2 years shelf life	Pale pink, round and biconvex, Diameter: 5.1 mm, shelf life 5 years	Pink, round, biconvex, 7 mm in diameter, shelf life 2 years	White to off-white, oblong, 10.3 – 10.4 mm in length, biconvex, 3 years shelf life
30mg	Brown, round, biconvex, 9mm in diameter, 2 years shelf life	Not available	Brown, round, approx. 8 mm diameter, 3 years shelf life	Brown, round, biconvex, 9mm, 2 years shelf life	Brown, round, approx. 8 mm diameter, 3 years shelf life	Not available	Brown, round, biconvex, 9 mm in diameter, shelf life 2 years	Not available
40mg	Yellow, round, biconvex, 7mm in diameter, 2 years shelf life	Yellow, round, biconvex, 6.8mm– 7.4mm, 5 years shelf life	Yellow, round, approx. 7 mm diameter, 3 years shelf life	Yellow, round, biconvex, 7mm, 2 years shelf life	Yellow, round, approx. 7 mm diameter, 3 years shelf life	Beige, round and biconvex, Diameter: 7.1 mm, shelf life 5 years	Yellow, round, biconvex, 7 mm in diameter, shelf life 2 years	Pink, oblong, 12.4 – 12.5 mm in length, biconvex, 3 years shelf life

Strength	Abtard MR tablets	Carexil MR tablets	Longtec MR tablets	Oxeltra MR tabs	Oxycontin MR tablets	Oxylan MR tablets	Reltebon MR tablets	Zomestine MR tablets
60mg	Red, round, biconvex, 9mm in diameter, 2 years shelf life	Not available	Red, round, approx. 8 mm diameter, 3 years shelf life	Red, round, biconvex, 9mm, 2 years shelf life	Red, round, approx. 8 mm diameter, 3 years shelf life	Not available	Red, round, biconvex, 9 mm in diameter, shelf life 2 years	Not available
80mg	Green, round, biconvex tablets, 9mm in diameter	Green, round, biconvex, 9.8mm – 10.4mm, 5 years shelf life	Green, round, approx. 9 mm diameter, 3 years shelf life	Green, round, biconvex, 9mm, 2 years shelf life	Green, round, approx. 9 mm diameter, 3 years shelf life	Pale green, round, diameter: 11.1 mm, shelf life 5 years	Green, round, biconvex, 9 mm in diameter, shelf life 2 years	Red, oblong, 15.6 – 15.7 mm in length, biconvex, 3 years shelf life
120mg	Not available	Not available	Purple, round, approx. 10 mm diameter, 3 years shelf life	Not available	Purple, round, approx. 10 mm diameter, 3 years shelf life	Not available	Not available	Not available

Table 13: Comparison of available formulations and size of oxycodone IR caps^{4,6}

Strength	Lynlor hard capsules	Oxynorm capsules	Shortec capsules
5mg	14.4 mm in length, with a dark pink body and a brown cap, 18 months shelf life	14.3mm in length orange/beige, 4 years shelf life	14.3mm in length orange/beige, 4 years shelf life
10mg	14.4 mm in length, with a white body and a brown cap, 18 months shelf life	14.3mm in length white/beige, 4 years shelf life	14.3mm in length white/beige, 4 years shelf life
20mg	14.4 mm in length, with a light pink body and a brown cap, 18 months shelf life	14.3mm in length pink/beige, 4 years shelf life	14.3mm in length pink/beige, 4 years shelf life