PrescQIPP Community Interest Company

Oxycodone

Nationally over £45.3 million is spent annually on oxycodone products. More than £6.8 million of this expenditure is for the higher strength oxycodone prolonged release (PR) products (ePACT March to May 2018). Medicines optimisation projects in this area are aimed at:

- Reviewing the continued need for oxycodone and decreasing/stepping down prescribed doses if appropriate.
- Switching to morphine sulfate (brand prescribed based on local formulary choice) if it has not been previously tried.
- Using brand prescribing of oxycodone immediate release (IR) or prolonged release (PR) products with the lowest acquisition cost (if unsuitable for a switch to morphine).

Support material is provided for organisations considering reviewing oxycodone including an audit and patient letters. Targinact® prescribing is covered in a separate bulletin, https://www.prescqipp.info/our-resources/bulletins/oxycodonenaloxone-targinact/

This project should also be used in conjunction with the PrescQIPP project on non neuropathic pain where additional information on pathways and patient agreements can also be found: https://www.prescqipp.info/our-resources/bulletins/bulletin-149-non-neuropathic-pain/

Recommendations

- Commence new patients requiring strong opioid therapy on morphine sulfate. Oxycodone can be considered as an option in patients who are intolerant of morphine sulfate, i.e. develop unacceptable side effects when taking morphine even when adjunct treatment is added to reduce these side effects or in renal impairment.[1]
- When initiating opioids, always consider a one to two week opioid trial (or long enough to observe the effect of opioids on two or three episodes of increased pain) to establish if the patient achieves a reduction in pain intensity and ability to achieve specific functional improvements (including sleep).[2] See PrescQIPP project and resources on non neuropathic pain (including pathway/contract): https://www.prescqipp.info/our-resources/bulletins/bulletin-149-non-neuropathic-pain/
- Review all patients currently on oxycodone tablets for suitability for switching to morphine sulfate. Switch all suitable patients to an appropriate formulation of morphine sulfate. As with all switches, these should be tailored to the individual patient. Prescribers should be aware of the difference in potency of oxycodone compared to morphine (morphine dose is 1.5 to 2 times oxycodone dose).
- Patients on oxycodone PR unsuitable for a switch to morphine sulfate should be switched to an equivalent dose of oxycodone PR, prescribed as a cost-effective brand.[3] CCGs should take into account the strengths available and manufacturer availability across different products.
- Patients on oxycodone IR should be switched to an equivalent dose of a cost effective branded oxycodone IR preparation, i.e. Shortec® or Lynlor®. IR products should only be used on a short term basis to titrate dose.
- Patients on long term opioid therapy for non-cancer pain should be reviewed regularly to assess whether there is a continued need for treatment with an opioid.

- To avoid confusion between the prolonged release products and standard release oxycodone products, all prolonged release oxycodone should be prescribed by brand.
- Review patients on high dose oxycodone (60mg daily dose or more which is equivalent to 120mg morphine or more) for suitability for step down treatment. Increasing opioid load above this dose is unlikely to yield further benefits but exposes the patient to increased harm. Consider specialist review.[2]
- Step down needs to be supported in order to be successful. Regular review of long term therapy should be at least annually and more frequently if problems arise.[2]
- Prescribers should be aware of the abuse potential of all opioids and careful consideration should be given when prescribing opioids for non-cancer pain to patients with a history of substance misuse or where abuse is a concern. Refer patients with a history of addiction involving opioids or other drugs to specialist services with expertise in pain medicine and addiction management.[2]

National guidance

The National Institute of Health and Care Excellence (NICE) clinical guideline 140[1] on the safe and appropriate prescribing of strong opioids for pain in adults with advanced and progressive disease was reviewed in July 2016 and found no major changes that would affect the recommendations over the next three to five years.

The guideline recommends morphine sulfate as the first line oral opioid of choice when initiating treatment and sustained release morphine sulfate as the strong oral opioid of choice for maintenance treatment. It also recommends that laxatives and/or antiemetic treatments are prescribed and optimised before considering changing oral opioid therapy. For patients experiencing drowsiness from therapy, NICE recommends either:

- Reducing the treatment dose if pain is controlled or
- Switching the opioid if pain is not controlled.[1]

There is no advice from NICE on the use of strong opioids for long term pain that is outside of palliative care.

The Scottish Intercollegiate Guidelines Network (SIGN) produced a guideline on the treatment of chronic pain in 2014 which states: “there is no clear evidence that any particular opioid including morphine is better than any other in terms of efficacy for pain relief although patients were more likely to discontinue buprenorphine than morphine because of lack of effect”.[4]

The Scottish Medicines Consortium has accepted oxycodone prolonged release (OxyContin®) for restricted use within NHS Scotland for the treatment of severe non-malignant pain requiring a strong opioid analgesic only when controlled release morphine sulfate is ineffective or not tolerated.[5]

The British Pain Society’s good practice guide for opioids for persistent pain states: “There is evidence from clinical trials that opioids can be effective, in the short and medium term, in providing symptomatic improvement in a variety of non-cancer pain conditions. However, the safety and efficacy of opioids in the long term is uncertain as is the propensity for these drugs to cause problems of tolerance, dependence and addiction. The benefits of opioid treatment for the patient must be balanced against burdens of long term use as therapy for persistent pain may need to be continued for months or years. The position of opioid treatment must also be considered within a wider social context and issues such as diversion must be addressed”.[6]

The Faculty of Pain Medicine[2] recommends that the use of immediate release preparations can provide effective symptomatic relief and use of such regimens may be justified when:

- The pain is intermittent and short-lived.
- Pain intensity varies significantly - use of regimens including immediate release preparations allows flexibility to reduce the dose on days when pain is or is expected to be less severe; or

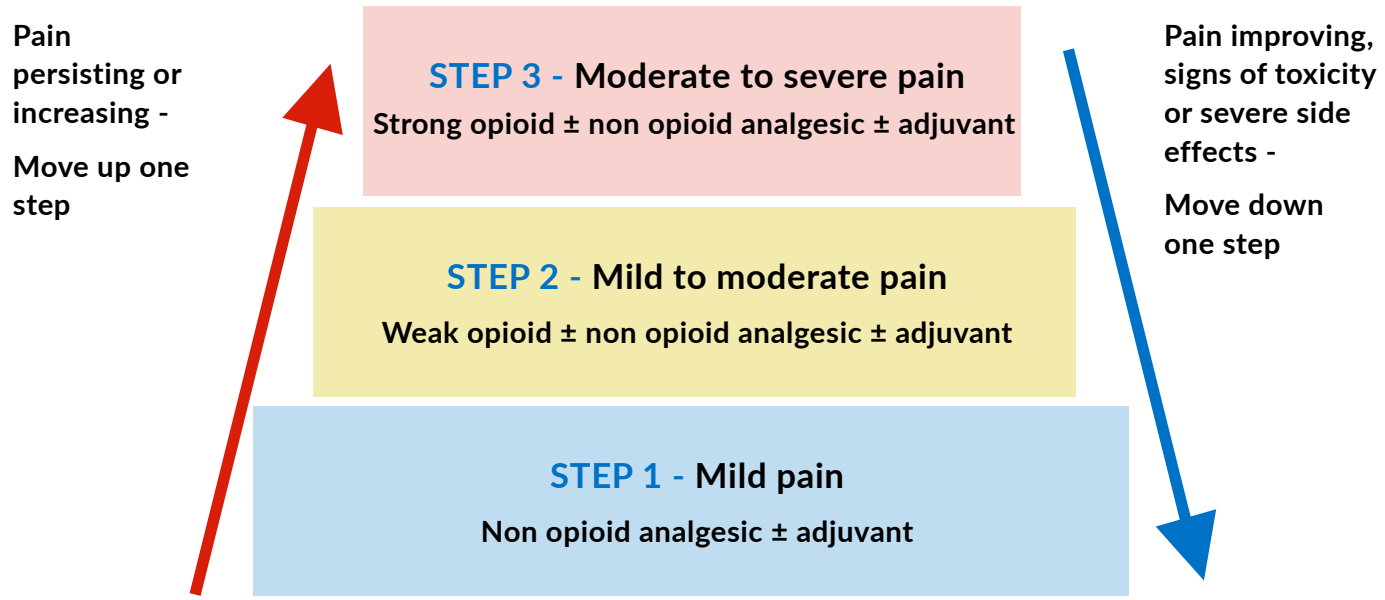
- Background pain that is well controlled with modified release preparations but the patient has infrequent, short-lived episodes of increased pain. Modified release opioids administered at regular intervals may be more appropriate for patients with persistent pain.

Clinical evidence

There is little evidence that one opioid is more effective and associated with fewer side effects than another. Non-morphine opioids, such as fentanyl, buprenorphine and oxycodone are significantly more expensive than oral morphine. There is no consistent evidence to suggest that non-morphine opioids are any more effective or show improved tolerability when compared with oral morphine.[2,6,7] Oral morphine should be the drug of first choice. However, there is a theoretical rationale for trying an alternative opioid if the first drug tried is helpful but causes intolerable side effects.[2,6]

Strong opioids should only be initiated in patients after non-opioid analgesics and mild opioid analgesics have been tried. This is particularly important in patients with non-cancer pain where careful consideration should be given before prescribing strong opioids.[1]

The World Health Organisation (WHO) recommends a ladder approach, as defined in diagram 1; this minimises the risk of respiratory depression and other adverse effects in opioid naïve patients. However, there have been criticisms to this approach, including that it does not address acute or non-persistent pain[2,4,8] – refer also to the non-neuropathic pain bulletin: https://www.prescqipp.info/our-resources/bulletins/bulletin-149-non-neuropathic-pain/



When a strong opioid is considered an appropriate treatment, morphine sulfate is widely considered as the first line strong opioid of choice. Patients are normally initiated with treatment on the immediate release formulations (given as a 4-6 hourly dose). Once their pain is controlled and the dose stabilised, the opioid can be converted to a twice-a-day sustained release formulation.[1,2,7]

Oxycodone and morphine are both strong opioids with similar efficacy and side effect profiles. A Cochrane review of 17 studies that analysed 1110 patients showed that oxycodone PR is as effective as other strong opioids including morphine sulfate MR in relieving chronic cancer-related pain, with similar adverse effect profiles. There have been limitations in the studies (all have been small and of short duration); no studies have demonstrated benefits of oxycodone over morphine sulfate.[9] There is a lack of evidence from high quality comparative trials that other opioids have advantages over morphine in terms of either efficacy or side effects.

A Cochrane review of oral and transdermal opioids for knee or hip osteoarthritis over a median duration of four weeks included ten trials of oxycodone. The review demonstrated a small or moderate benefit

for oxycodone. The authors conclusion was that "The small mean benefit of non-tramadol opioids is contrasted by significant increases in the risk of adverse events. For the pain outcome in particular, observed effects were of questionable clinical relevance since the 95% Confidence Interval (CI) did not include the minimal clinically important difference of 0.37 standardised mean differences (SMDs), which corresponds to 0.9 cm on a 10cm visual analogue scale (VAS)".[10]

A further Cochrane review concluded that there was only one very low quality evidence study that oxycodone PR was of value in the treatment of painful diabetic neuropathy or postherpetic neuralgia versus placebo. There was no evidence for other neuropathic pain conditions. Adverse events typical of opioids appeared to be common.[11]

Safety of opioids

In 2008, the National Patient Safety Agency (NPSA) published a Rapid Response Report highlighting patient safety incidents concerning dosing errors with opioid medicines.[12] This report was based on a number of incidents reported where patients had received incorrect doses or formulations of opioid medicines based on their previous doses.

The recommendations in this report were that previous doses of treatment should be confirmed when prescribing, dispensing or administering opioid medicines and that dose increments should be safe for the patient and no more than 50% of the previous dose for oral morphine and oxycodone. The report also recommended that prescribers should be familiar with the following characteristics of the medicines and formulations used: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

The report went on to say "While dose increments should be in line with this guidance, it is recognised that in palliative care higher than normal doses may be required. These recommendations are not designed to restrict clinical use of opioid medicines, but to ensure they are used in a way that is as safe as possible for patients." Approximately 15% (ePACT March to May 2018) of items prescribed are for the very high doses of oxycodone and in light of the recommendations by the NPSA, these patients should be reviewed if they are not palliative care patients.

Patients with chronic non-cancer pain who are prescribed and are taking opioids can have a history of long term high dose opioid use without effective pain relief. In those without good pain relief, reduction of the prescribed opioid dose may be the desired and shared goal of both the patient and clinician. Simple unsupervised reduction of opioid use is clinically challenging, and very difficult to achieve and maintain.[13]

There have been reports of errors/confusion between standard and PR oxycodone where patients have had OxyContin® (oxycodone PR) dispensed/prescribed instead of OxyNorm®, the standard release preparation of oxycodone, which can lead to fatal overdoses if taken four times a day. It is therefore recommended that oxycodone always be prescribed by brand name to avoid confusion and errors.[14]

Morphine and oxycodone have an abuse profile similar to other strong opioids.[7,15,16] Opioid analgesics may be sought and abused by people with addiction disorders and there is potential for development of addiction to prescribed opioid analgesics. Opioid analgesics should be used with particular care in patients with a history of alcohol and drug abuse. Tampering with tablets is also popular among individuals seeking the euphoric properties of opioids. By crushing and snorting, or dissolving and injecting, individuals receive a much higher and immediate dose of opioid than they would if they swallowed the tablet whole. This is widely documented on chat forums where people addicted to these drugs seek advice on how to tamper with them.

Conversions

It is difficult to determine a precise equivalent dose for oxycodone to morphine as reported equi-analgesic dose ratios vary widely. When converting from one opioid to another, regular assessment

and reassessment of efficacy and adverse effects is essential because of the lack of evidence on equi-analgesic doses and inter-individual variation.

The summary of product characteristics (SPC) for OxyContin® states that: "Patients receiving oral morphine before OxyContin® therapy should have their daily dose based on the following ratio: 10mg of oral oxycodone is equivalent to 20mg of oral morphine. It must be emphasised that this is a guide to the dose of OxyContin® tablets required. Inter-patient variability requires that each patient is carefully titrated to the appropriate dose".[15]

However, the BNF states 6.6mg of oral oxycodone is equivalent to 10mg of oral morphine.[7]

Drug	SPC[15]	BNF[7]	Faculty of Pain Medicine[2]
Morphine equivalent	10	10	10
Oxycodone	5	6.6	5

It is important to review all patients that need to be switched to an equivalent dose of 120mg oral morphine equivalent/24 hours, e.g. 30mg oxycodone twice daily (60mg oxycodone per day). Increasing opioid load above this dose is unlikely to yield further benefits but exposes the patient to increased harm. Consider specialist review.[2]

Costs

There is a significant difference in cost between different brands of oxycodone and between morphine sulfate modified release products and oxycodone PR or Targinact® products. Tables 1 and Table 2 illustrate the cost differences between different brands of oxycodone IR and oxycodone PR preparations.

All the brands of oxycodone are twice daily except for Onexila® XL which is once daily. A very small study of 68 patients with chronic malignant or non malignant pain over five days only, showed no difference in analgesia between oxycodone once daily MR tablet to the established oxycodone twice daily prolonged release tablet at equivalent daily doses.[17]

Table 1: Cost of generic and branded IR oxycodone capsules

Product	Drug Tariff	Lynlor®	Shortec®	Oxynorm®
Oxycodone 5mg x 56	£11.43	£6.86	£6.86	£11.43
Oxycodone 10mg x 56	£22.86	£13.72	£13.72	£22.86
Oxycodone 20mg x 56	£45.71	£27.43	£27.43	£45.71

Table 2: Comparison of 28 days costs of oxycodone PR branded tablets[3,7]

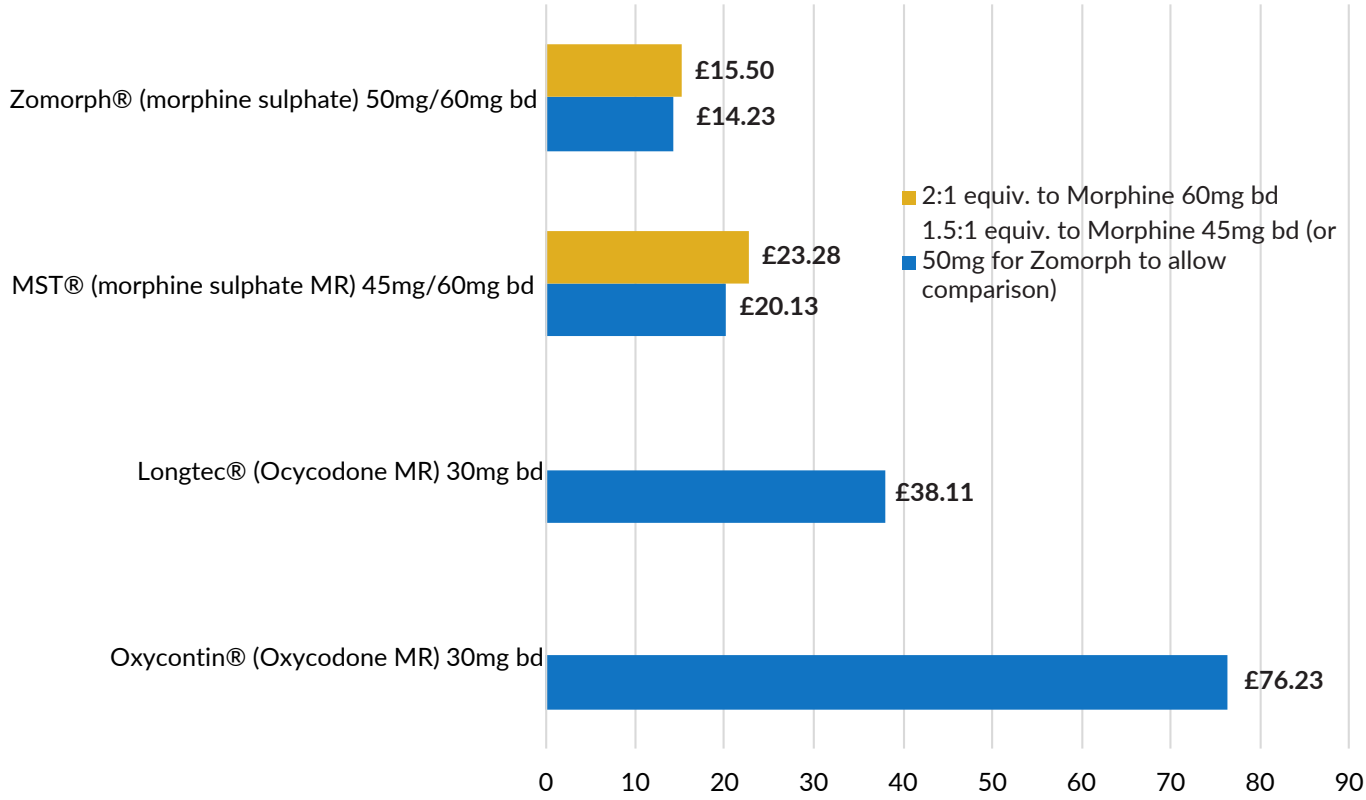
Product	5mg	10mg	15mg	20mg	30mg	40mg	60mg	80mg
Twice daily preparations (cost for 56 tablets)								
Drug Tariff price	£12.52	£25.04	£38.12	£50.08	£76.23	£100.19	£152.49	£200.39
Longtec PR	£12.52	£12.52	£19.06	£25.04	£38.11	£50.09	£76.24	£100.19
Abtard PR	£12.52	£12.52	£19.06	£25.04	£38.11	£50.09	£76.24	£100.19
Carexil PR	£12.52	£25.04	-	£25.04	-	£60.11	£86.24	£120.23

Product	5mg	10mg	15mg	20mg	30mg	40mg	60mg	80mg
Twice daily preparations (cost for 56 tablets)								
Leveraxo PR	£24.78	£24.79	-	£49.58	£75.47	£99.19	£150.97	£198.39
Oxeltra PR	£22.54	£22.54	£34.31	£45.07	£68.61	£90.17	£137.24	£180.35
Oxycontin PR	£25.04	£25.04	£38.12	£50.08	£76.23	£100.19	£152.49	£200.39
Zomestine PR	£10.02	£10.02	-	£20.03	-	£40.08	-	£80.16
Reltebon PR	£12.52	£12.52	£19.06	£25.04	£38.11	£50.09	£76.24	£100.19
Once daily preparations (cost for 28 tablets)								
Onexila XL	-	£12.52	-	£12.52	-	£25.04	-	£50.09

Table 3: Comparison of oxycodone PR and morphine MR[3,7]

Morphine sulfate modified release 28 day cost **(Dose: One tablet or capsule twice daily – least costly brand stated)**			**Oxycodone prolonged release 28 day cost** **(Dose: One tablet twice daily – least costly brand stated). For other brands see table 2.**		
Morphine sulfate strength	**Generic tablets/MST® Continus tablets**	**Generic capsules/ Zomorph® capsules**	**Equivalent strength to morphine (2:1)**	**Generic tablets/ OxyContin®**	**Longtec®**
5mg	£3.07				
10mg	£5.04	£3.24	5mg	£25.04	£12.52
15mg	£8.49				
			10mg	£25.04	£12.52
30mg	£11.64	£7.75	15mg	£38.12	£19.06
			20mg	£50.08	£25.04
60mg	£22.70	£15.12	30mg	£76.23	£38.11
			40mg	£100.19	£50.09
			60mg	£152.49	£76.24
100mg	£35.93	£20.35			
			80mg	£200.39	£100.19
200mg	£75.92	£40.69			

Chart 1: 28 day cost for 30mg dose oxycodone prolonged release compared to 45mg (1.5x) and 60mg (2x) conversion to morphine sulfate modified release



Switching options and savings available (ePACT March to May 2018)

There are several potential switch/review options for oxycodone products (although clinicians may choose other options according to the clinical need of the patient). Savings calculations shown below are across England and Wales. These include:

- Oxycodone PR to morphine sulfate MR
  - For patients that have not previously tried morphine sulfate, switching all oxycodone PR product prescriptions to morphine sulfate MR 12 hourly tablets or capsules (Zomorph® capsules are the lowest cost product, MST Continus® is the most commonly prescribed tablet) **could save up to £9.8 million annually which equates to £16,589 per 100,000 patients**.
  - Switch doses will need to be agreed locally between GPs, medicines management teams and pain specialists. It is advisable to use a lower dose ratio for the switch (morphine sulfate MR at 1.5 times the oxycodone PR dose) and add morphine sulfate oral solution for breakthrough pain if needed. The dose of morphine sulfate can then be titrated up after review. Palliative care patients should not be switched.
  - Additional costs of laxatives or anti emetics (if needed and not already prescribed) would be minimal and offset against these savings.
- Oxycodone PR to lower cost branded generic oxycodone
  - For patients where morphine sulfate would not be suitable, consider a switch where appropriate to an equivalent or appropriate dose of a cost effective branded generic oxycodone product (branded oxycodone PR).
  - **Total annual savings for switching oxycodone MR to Longtec® (or another cost-effective product) are £5.9 million annually which equates to £10,099 per 100,000 patients.**
  - CCGs should consider the strengths of formulations available and product availability when deciding on which formulation to use.

- Oxycodone IR
  - » A switch of oxycodone IR to Shortec®/Lynlor® **could result in total annual savings of £1.4 million annually which equates to £2,498 per 100,000 patients**.

Review

Use of opioid analgesics should be reviewed regularly. If the doctor and patient agree at a review that If at review the prescribing of an opioid analgesic is no longer appropriate, then therapy should be tapered down and discontinued. Non-opioid analgesia may be appropriate in some patients. **A reduction of 30% of oxycodone PR prescribing could save approximately £15.1 million annually which equates to £20,408 per 100,000 patients.**

Higher doses of oxycodone PR are very expensive and on an individual patient basis can cost over £3,000 per year. Almost 4% of items are for higher strengths of oxycodone (80mg and 120mg) and account for £1.7 million annual spend (15% of the costs). These patients should be reviewed and attempts made to reduce their daily dose of opioids if possible (consider specialist support).

The savings above illustrate the maximum savings available. In reality, the total amount may not be achieved as different options will be suitable for different patients. The data pack attached shows prescribing data at CCG level and annual savings available for each CCG for the above switches.

Savings have been calculated using a rough approximation of:

- Morphine sulfate MR being approximately 80% cheaper than oxycodone PR on average across all doses and formulations and
- Longtec® being approximately 50% cheaper than Oxycontin®/Oxynorm®/generically prescribed oxycodone PR on average across all doses.

Full data pack available here https://pdata.uk/#/views/B213_Oxycodoneupdate/FrontPage?:iid=1

Summary

There is no evidence to suggest that oxycodone has advantages in efficacy and tolerability over morphine sulfate, however it is significantly more costly. Prescribing levels are increasing and there are concerns over its abuse potential and illicit use on the black market (as is the case with all opioids). Switching treatment from oxycodone to morphine sulfate can lead to significant savings. If morphine sulfate is unsuitable for the patient then switching treatment to a more cost effective branded generic product e.g. Longtec® for PR preparations or Shortec® for IR preparations will create savings.

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Additional PrescQIPP resources

Briefing

Audit, patient review letter, switch letters

Available here: https://www.prescqipp.info/our-resources/bulletins/bulletin-213-oxycodone/

Data pack

Available here: https://pdata.uk/#/views/B213_Oxycodoneupdate/FrontPage?:iid=1

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Contact help@prescqipp.info with any queries or comments related to the content of this document.

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