Expert peer review on application for OXYCODONE

Oxycodone is a synthetic phenanthrene-derivative opiate agonist

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      1. Pain: Conventional preparations of oxycodone hydrochloride/hydrochloride and terephthalate are used orally for management of moderate to moderately severe pain in: bursitis, injuries, dislocations, simple fractures and neuralgias, postoperative, post-extractional and postpartum pain
      2. Extended release preparation of oxycodone hydrochloride are used orally for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time such as: cancer pain and nonmalignant pain, back pain, osteoarthritis related pain and pain during rehabilitation following total knee arthroplasty. Oxycodone extended release tablet are indicated for postoperative use only in patients receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and to persist for an extended period of time
   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes
   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      1. Although adverse effects are milder than those of morphine, addiction liability of oxycodone is about the same as that of morphine.
      2. Oxycodone has been intentionally abused by crushing extended-release preparations and “snorting” the powder or dissolving the content in water and injecting the solution IV. Abuse by chewing extended-release preparation also has been reported. Breaking, chewing or crushing of extended-release oxycodone preparations results in immediate release of the opiate and the risk of a potentially fatal overdose
      3. The risk of toxicity is increased when used concomitantly with alcohol or other CNS depressants, including other opiates
      4. FDA approved a REMS (Risk Evaluation and Mitigation Strategy) for oxycodone to ensure that the benefits of a drug overweight the risk
5. Misuse and Abuse:
Oxycodone has emerged as one of the most problematic abuse opiate agonist, therefore, patients should be advised about the risk of theft, and clinicians should be informed about abuse and diversion issues.

c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
a. Have all relevant data on safety provided
   Yes
b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
   In comparison with Morphine hydrochloride, the cost of oxycodone is higher.

c. Please provide any additional relevant information with reference

d. Is the product available in several low and middle income countries?
   Oxycodone preparations, specially extended release preparations, should be imported from industrialized countries to low and middle income countries.

4. Assessment of public health need
a. Please provide the public health need for this product (1-2 sentences)
   Oxycodone as other opioid preparations (tablet and injectable) are drugs needed for public health to treat intense pain and pain not responsive to other analgesics for: Post-traumatic patients, post-operative patients, cancer patients and for anesthesia and pre-anesthesia

b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable
   No

5. Are there special requirements for use or training needed for safe/effective use?
   If yes, please provide details in 1-2 sentences

   Due to narcotic addition is a current social evil in many countries, it is necessary:
   1. To train the health staff to implement the Guidelines/Treatment Regimen relating narcotic safe/effective use for medical purposes
   2. To promulgate document and training materials for safe/effective use morphine and opioid pharmaceutical products and narcotic products
   3. To conduct control/inspection activities relating narcotic products
   4. To supervise the implementation of Narcotic Law and regulatory documents relating narcotics
   5. To advise the patients about the risk of theft, the clinicians about abuse and diversion issues

6. Is the proposed product registered by a stringent regulatory authority?
   Yes
   National Medicines Administration Authority and Narcotic Control Authority
7. Any other comments

8. What is your recommendation to the committee (please provide the rationale)

Oxycodone could be listed in WHO EML (complementary list) due to the higher efficacy and lesser ADR than morphine but high cost and unavailable generic products in low and middle income country.

Need to train the health staff for safe and rational use under strict control measures against the misuse and abuse of oxycodone products