DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY: Oral Long-Acting Opioids Duration Limit for 30-Day Period

DATE REVIEWED: 06/04/2019

DRUGS AFFECTED:

- hydrocodone bitartrate extended-release capsules (Zohydro® ER – Zogenix)
- hydrocodone bitartrate extended-release tablets (Hysingla™ ER – Purdue Pharma)
- hydromorphone hcl extended-release tablets (Exalgo® – Mallinckrodt, generics)
- morphine sulfate and naltrexone hydrochloride (Embeda® – Pfizer)
- morphine sulfate controlled-release tablets (MS Contin® - Purdue Pharma, generics)
- morphine sulfate extended-release capsules (generics [Avinza® - King – no longer manufactured])
- morphine sulfate extended-release capsules (Kadian® - Actavis, generics)
- morphine sulfate sustained release tablets (generics [Oramorph® SR – Xanodyne – no longer manufactured])
- morphine sulfate extended release tablets (Arymo™ ER – Egalet US Inc)
- morphine sulfate extended release tablets (Morphabond™ ER – Daiichi Sankyo, Inc.)
- oxycodone hcl controlled-release tablets (Oxycontin® – Purdue Pharma, branded generics)
- oxycodone base extended-release capsules (Xtampza ER – Collegium Pharmaceutical, Inc)
- oxymorphone hcl extended-release tablets (Opana® ER – Endo)
- tapentadol extended-release oral tablets (Nucynta® ER – Janssen)

OVERVIEW

Table 1. Quantity Level Limits

Medication Name and Strength	***Per Days Quantity Level Limit***
Avinza, generics 30 mg, 45 mg, 60 mg, 75 mg, 90 mg and 120 mg capsules	60 capsules per 30 days
Embeda 20 mg/0.8 mg, 30 mg/1.2 mg, 50 mg/2 mg, 60 mg/2.4 mg, 80 mg/3.2 mg and 100 mg/4 mg capsules	90 capsules per 30 days
Exalgo, generics 8 mg, 12 mg, 16 mg and 32 mg tablets	60 tablets per 30 days
Kadian, generics (select strengths) 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 80 mg, 100 mgand 200 mg capsules	90 capsules per 30 days
MS Contin, generics 15 mg, 30 mg, 60 mg, 100 mg and 200 mg tablets morphine sulfate SR, generics 15 mg, 30 mg, 60 mg, and 100 mg tablets Arymo ER 15 mg, 30 mg, 60 mg tablets Morphabond ER 15 mg, 30 mg, 60 mg, and 100 mg tablets	120 tablets per 30 days Limits for MS Contin, Arymo ER, Morphabond ER and morphine sulfate SR accumulate. (e.g., if pt. already filled 60 tabs of MS Contin, only 60 tabs of Arymo ER or morphine sulfate SR will be available).
Nucynta ER 50 mg, 100 mg, 150 mg, 200 mg and 250 mg tablets	60 tablets per 30 days
Opana ER, generics 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg and 40 mg tablets	90 tablets per 30 days
Oxycontin 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg tablets Xtampza ER 9 mg, 13.5 mg, 18 mg, 27 mg and 36 mg	90 tablets/capsules per 30 days Limits for Oxycontin and Xtampza ER accumulate. (e.g., if pt. already filled 60 tabs

capsules	of Oxycontin, only 30 tabs of Xtampza ER will be available).
Hysingla ER 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, and 120 mg tablets Zohydro ER 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg capsules	60 tablets per 30 days 90 capsules per 30 days Limits for Hysingla ER and Zohydro ER accumulate. (e.g., if pt. already filled 60 tabs of Hysingla ER, only 30 tabs of Zohydro ER will be available).

Opioid analgesics have a central role in the management of moderate to severe pain. Opioids have been considered the mainstay of cancer pain management and they are increasingly used for treatment of chronic and acute noncancer pain. Controlled-release oral opioids offer a long duration of action which lessens the severity of end-of-dose pain and often allows patients to sleep through the night. With controlled-release opioids, some patients report decreased effectiveness during the last few hours of the recommended dosing interval. Such instances of end-of-dose breakthrough pain usually respond to shortening the dosing interval. In addition, long-acting opioids should be prescribed with an immediate-release product to be used as needed for breakthrough pain.[1-2]

A quantity of each medication as listed in Table 1 is limited to 30 days and will be covered without prior authorization. The quantity limit is specific to each chemical entity for all strengths combined. The limit is combined for MS Contin, Arymo ER, Morphabond ER and morphine sulfate SR because they contain the same active ingredient and the generics are used interchangeably. Limits for Hysingla ER and Zohydro ER will accumulate (e.g., if pt. already filled 60 tabs of Hysingla, only 30 tabs of Zohydro will be available) (please refer to Table 1). In addition, limits for Oxycontin and Xtampza ER will accumulate (e.g., if pt. already filled 60 tabs of Oxycontin, only 30 tabs of Xtampza ER will be available) (please refer to Table 1). .For coverage of additional quantities, prior authorization is required. The objective of this coverage rule is to prevent stockpiling, misuse and/or overuse of controlled release opioids.

The current ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS), which was originally approved in 2012 requires manufacturers to provide educational programs to health care professionals on how to safely prescribe opioids, as well as to provide Medication Guides and patient counseling documents. The REMS was updated to reflect the September 2013 labeling changes.

In March 2016, the CDC published a Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. The guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. The intent of the guideline is to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.

Arymo ER
Arymo ER is available as 15 mg, 30 mg and 60 mg tablets. Arymo ER is extended-release formulation of morphine sulfate indicated for the management of pain that is severe enough to require daily, around-the-

clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). Arymo ER can be administered on either an every twelve hour or every eight hour schedule. Patients who are not opioid tolerant and those starting morphine sulfate ER as the first long-acting opioid should begin individual therapy titration with the 15 mg tablet every 8 or 12 hours. Patients receiving other oral morphine formulations may be converted to Arymo ER by administering one-half of the patient's 24-hour requirement as Arymo ER on an every-12-hour schedule or by administering one-third of the patient's daily requirement as Arymo ER on an every-8-hour schedule. A single dose of Arymo ER greater than 60 mg, or a total daily dose greater than 120 mg, are only for use in patients in whom tolerance to an opioid of comparable potency has been established. Arymo ER tablets are to be swallowed whole and are not to be broken, chewed, dissolved or crushed.[15]

Avinza (generic)
Avinza is available as 30 mg, 45 mg, 60 mg, 75 mg, 90 mg and 120 mg capsules. Avinza is a modified-release oral formulation of morphine sulfate intended for once daily administration. Avinza is indicated for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). Avinza is not intended for use as an as-needed analgesic. The extended release formulation allows Avinza to be administered every 24 hours. Patients who are not opioid tolerant and those starting Avinza as the first long-acting opioid should begin individual therapy titration with the 30 mg capsule. The prescribing information contains conversion information for patients changing from immediate-release morphine or methadone to Avinza, but the 30 mg starting dose is recommended for patients changing from another oral or parenteral opioid to Avinza. The dose of Avinza must be limited to a maximum of 1600 mg per day as doses above this maximum contain a quantity of fumaric acid that have not been demonstrated as safe which could result in renal toxicity. Avinza capsules are to be swallowed whole or the contents of the capsule may be sprinkled on applesauce. The capsule beads are not to be chewed, crushed or dissolved.[3]

Embeda
Embeda is available as 20 mg/0.8 mg, 30 mg/1.2 mg, 50 mg/2 mg, 60 mg/2.4 mg, 80 mg/3.2 mg and 100 mg/4 mg capsules. Embeda is an extended-release oral formulation of morphine sulfate and naltrexone hydrochloride indicated for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). Patients who are not opioid tolerant should begin with a dose of 20 mg/0.8 mg every 24 hours. Embeda may be administered once or twice daily. Patients who experience inadequate analgesia on once-daily dosing may be switched to twice daily dosing. Embeda is not intended for use as an as-needed analgesic. Additionally, Embeda is not indicated for acute pain or if the pain is mild or not expected to persist for an extended period of time. The 100 mg/4 mg capsules, single dose greater than 60 mg/2.4 mg, or a total daily dose greater than 120 mg/5 mg are only for use in opioid-tolerant patients. Embeda capsules are to be swallowed whole or the contents of the capsules sprinkled on applesauce and taken by mouth. The pellets in the capsules are not to be crushed, dissolved or chewed before swallowing.[4]

Exalgo (generic)
Exalgo is available as 8 mg, 12 mg, 16 mg and 32 mg tablets. Exalgo is an extended-release oral formulation of hydromorphone hydrochloride indicated the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). Exalgo can be administered every 24 hours and is only recommended for opioid-tolerant patients. The dose range studied in clinical trials was 8 mg to 64 mg once daily. The prescribing information contains conversion information for patients converting from immediate-release hydromorphone or another opioid to Exalgo. Exalgo is not indicated for the management of acute pain or if the pain is mild or not expected to persist for an extended period of

time. Exalgo is not intended to be used as an as needed analgesic. Exalgo should be swallowed whole and should not be broken, crushed, dissolved or chewed before swallowing.[5]

Kadian (generic)
Kadian is available as 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 80 mg, 100 mg**,** and 200 mg capsules. Kadian is an extended-release oral formulation of morphine sulfate indicated for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). Kadian may be administered once or twice daily. Patients who are excessively sedated after a once-a-day dose or who regularly experience inadequate analgesia before the next dose may be switched to a twice-a-day dosing. Kadian is not intended for use as an as-needed analgesic. Additionally, Kadian is not indicated for acute pain or if the pain is mild or not expected to persist for an extended period of time. Patients who are not opioid tolerant and those starting Kadian as the first long-acting opioid should begin individual therapy titration with the 30 mg capsule. The prescribing information contains conversion information for patients changing from immediate-release morphine or methadone to Kadian, but the 30 mg starting dose is recommended for patients changing from another opioid to Kadian. Kadian 100 mg and 200 mg are for use in opioid-tolerant patients only. Kadian capsules are to be swallowed whole or the contents of the capsule may be sprinkled on applesauce. The pellets in the capsule are not to be chewed, crushed or dissolved.[6]

Morphabond ER
Morphabond ER is available as 15 mg, 30 mg, 60 mg and 100 mg tablets. Morphabond ER is an extended-release formulation of morphine sulfate indicated for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). Morphabond ER is administered on an every twelve hour schedule. Patients who are not opioid tolerant and those starting morphine sulfate ER as the first long-acting opioid should begin individual therapy titration with the 15 mg tablet every 12 hours. Patients receiving other oral morphine formulations may be converted to Morphabond ER by administering one-half of the patient's 24-hour requirement as Morphabond ER on an every-12-hour schedule. A single dose of Morphabond ER greater than 60 mg, or a total daily dose greater than 120 mg, are only for use in patients in whom tolerance to an opioid of comparable potency has been established. Morphabond ER tablets are to be swallowed whole and are not to be broken, chewed, dissolved or crushed.[16]

MS Contin & morphine sulfate SR
MS Contin and morphine sulfate SR are available as 15 mg, 30 mg, 60 mg, 100 mg and 200 mg (MS Contin only) tablets. MS Contin is "controlled-release" and morphine sulfate SR is "sustained release": both are extended-release (ER) oral formulations of morphine sulfate indicated for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). Morphine sulfate ER can be administered on either an every twelve hour or every eight hour schedule. Patients who are not opioid tolerant and those starting morphine sulfate ER as the first long-acting opioid should begin individual therapy titration with the 15 mg tablet every 8 to 12 hours. The prescribing information contains conversion information for patients changing from immediate-release morphine or methadone to morphine sulfate ER, but the 15 mg every 8 to 12 hours starting dose is recommended for patients changing from another opioid to Morphine sulfate ER. MS Contin 100 mg and 200 mg tablets and morphine sulfate SR 100 mg tablets are for use in opioid-tolerant patients only. Morphine sulfate ER tablets are to be swallowed whole and are not to be broken, chewed, dissolved or crushed.[7, 12]

Nucynta ER
Nucynta ER is available as 50 mg, 100 mg, 150 mg, 200 mg and 250 mg tablets. Nucynta ER is an extended-release formulation of tapentadol indicated for the management of pain that is severe enough

[including neuropathic pain associated with diabetic peripheral neuropathy (DPN)] to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). Nucynta ER can be administered twice daily, approximately every 12 hours. The maximum recommended daily dose of Nucynta ER is 500 mg. Patients who are not opioid tolerant and those starting Nucynta ER as the first long-acting opioid should begin individual therapy titration with the 50 mg tablet twice daily. The prescribing information contains conversion information for patients changing from immediate-release Nucynta or another oral opioid to Nucynta ER. Nucynta is not intended for use as an as needed analgesic. Nucynta ER is not intended for the management of acute or postoperative pain. Nucynta ER tablets should be swallowed whole and not split, broken, chewed, dissolved, or crushed.[8]

Opana ER (generic)
Opana ER is available as 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg and 40 mg tablets. Opana ER is an extended-release oral formulation of oxymorphone hydrochloride indicated for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). Opana ER is to be administered twice daily (every 12 hours). Patients who are not opioid tolerant and those starting Opana ER as the first long-acting opioid should begin individual therapy titration with the 5 mg tablet twice daily. The prescribing information contains conversion information for patients changing from immediate-release oxymorphone or another oral opioid to Opana ER. Opana ER is not intended for use as an as needed analgesic. Additionally, Opana ER is not indicated for acute pain or if the pain is not expected to persist for an extended period of time. Opana ER is contraindicated in patients with moderate and severe hepatic dysfunction. Opioid naïve patients with mild hepatic impairment or a creatinine clearance rate less than 50 mL/min should be started with the lowest dose and titrated slowly while carefully monitoring side effects, opioid tolerant patients' doses should be decreased by 50% compared to those for patients with normal hepatic and renal function. Opana ER tablets are to be swallowed whole, and are not to be broken, chewed, crushed or dissolved.[9]

Oxycontin & Xtampza ER
Oxycontin is available as 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg tablets and Xtampza ER is available as 9 mg, 13.5 mg, 18 mg, 27 mg and 36 mg capsules. Xtampza ER is formulated with oxycodone base. The following table provides equivalent doses of oxycodone base (Xtampza ER) to oxycodone hydrochloride.

Oxycodone Hydrochloride	Oxycodone base (XTAMPZA ER)
10 mg	9 mg
15 mg	13.5 mg
20 mg	18 mg
30 mg	27 mg
40 mg	36 mg

Oxycontin and Xtampza ER are controlled-release oral formulations of oxycodone indicated for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids).

The controlled release formulations allow Oxycontin and Xtampza ER to be administered every 12 hours. Xtampza ER must be taken with food. The contents of Xtampza ER capsules can be opened and sprinkled on food if they are unable to swallow the capsule. Patients who are not opioid tolerant and those starting Oxycontin as the first long-acting opioid should begin individual therapy titration with the 10 mg

tablet twice daily. Xtampza ER should be initiated with the 9 mg capsules every 12 hours if the patient is opioid-naïve or opioid intolerant.

The prescribing information contains conversion information for patients changing from immediate-release oxycodone or methodone. It is recommended that patients who are converting from another oral opioid to Oxycontin begin with the 10 mg tablet twice daily dosing. Oxycontin is not intended for use as an as needed analgesic. In patients with hepatic impairment, Oxycontin should be initiated at one-third to one-half usual starting doses with a careful titration schedule. In patients with renal impairment (CrCl < 60 ml/min), dose initiation should follow a conservative approach. Oxycontin 60 mg and 80 mg tablets, single doses greater than 40 mg, and total daily doses greater than 80 mg are for use in opioid-tolerant patients only. Oxycontin tablets are to be swallowed whole and are not to be broken, chewed, crushed, or dissolved.[11] Patients converting from other oral oxycodone formulations may be converted to Xtampza ER, using the same total daily dose of oxycodone, by administering one-half of the patient's total daily oral dose every 12 hours. There is conversion information in the prescribing information for patients changing from other opioids and methadone. Xtampza ER is not indicated as an as-needed analgesic. Xtampza ER single doses greater than 36 mg (equivalent to 40 mg oxycodone hydrochloride [HCl]) or a total daily dose greater than 72 mg (equivalent to 80 mg oxycodone HCl) are to be administered only to patients in whom tolerance to an opioid of comparable potency has been established. Patients considered opioid tolerant are those receiving, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone HCl per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid. The maximum daily dose of Xtampza ER is 288 mg per day as the safety of the excipients in Xtampza ER for doses over 288 mg/day has not been established. For patients with hepatic impairment, start dosing patients at 1/3 to 1/2 the usual starting dose followed by careful dose titration.

Hysingla ER & Zohydro ER
Hysingla ER is available as 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, and 120 mg tablets and Zohydro ER is available as 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg capsules.[11, 13] Both Hysingla ER and Zohydro ER are extended-release oral formulations of hydrocodone bitartrate indicated for the management of pain that is severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate (non-opioid analgesics or immediate-release opioids). These medications are not intended for use as an as-needed analgesics. The extended release formulation allows Hysingla ER to be administered once every 24 hours and Zohydro ER to be administered every 12 hours. Patients who are not opioid tolerant and those starting one of these medications as the first long-acting opioid should begin individual therapy titration with the lowest available strength dosage form (that is, 20 mg Hysingla ER once every 24 hours or 10 mg Zohydro ER every 12 hours). The prescribing information for each product contains conversion information for patients changing from another oral opioid to Hysingla ER or Zohydro ER. For Hysingla ER, no initial dose adjustment is required in patients with mild or moderate hepatic or mild renal impairment, but in patients with more severe impairment may experience higher plasma concentrations and therefore it is recommended that therapy be initiated at half the initial dose. For Zohydro ER, no initial dose adjustment is required in patients with hepatic or renal impairment, but patients should be monitored closely, as plasma concentrations may be higher than in patients with normal function. Single doses of Zohydro ER 40 mg, 50 mg, or a total daily dose of greater than 80 mg are for use in opioid-tolerant patients only. Likewise, daily doses greater than or equal to 80 mg of Hysingla ER are for use in opioid tolerant patients. Hysingla ER tablets and Zohydro ER capsules are to be swallowed whole. Chewing, crushing or dissolving will result in uncontrolled delivery of hydrocodone and can lead to overdose or death.[11,13]

CRITERIA

Nucynta ER 200 mg and 250 mg
No exceptions recommended. The maximum recommended daily dose of Nucynta ER is 500 mg.[8]

Arymo ER, Avinza, Embeda, Exalgo (generics), Kadian (generics), MS Contin (generics), Morphabond ER, Oramorph SR (generics), Nucynta ER (50 mg, 100 mg, 150 mg), Opana ER (generics), Oxycontin, Hysingla ER, ,Zohydro ER and Xtampza ER

1. **Intractable pain** (defined as pain that is difficult to manage, alleviate, remedy, or cure, is sustained and persistent rather than brief and intermittent, and interferes with activities of daily living) from a chronic condition (e.g., current diagnosis of cancer, low back pain, musculoskeletal pain, sickle cell pain),
   THEN
   Authorize a quantity limit override to allow up to the prescribed quantity per 30 day period for a duration of 6 months. NOTE: Quantity overrides are not to exceed 1600 mg per day for Avinza, 500 mg per day for Nucynta ER, or 288 mg per day for Xtampza ER .

2. **Acute pain** including surgery/post-surgery, trauma/post-trauma, acute medical illness (e.g., acute abdominal pain, pelvic pain, muscle spasm). Authorization for quantity overrides is *not* recommended.

3. **As-needed analgesia.** Overrides are *not* recommended for patients taking long acting opioids on an as needed (prn) basis.

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