Pharmacy Policy Bulletin

Title: Controlled Substance Prior Authorization

Policy #: Rx.01.15

Application of pharmacy policy is determined by benefits and contracts. Benefits
may be subject to precertification, age, gender or quantity restrictions. Individual

This pharmacy policy document describes the status of pharmaceutical informatio
that time, new information relating to drug efficacy, interactions, contraindications
changed. This Pharmacy Policy will be regularly updated as scientific and medical
approved indications, withdrawals, or other FDA alerts. This type of information is
updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highe

Intent:

Opioid analgesics (**controlled substances)** are indicated for the treatment of pain. The
opioid analgesics which will also be referred to as narcotic medications, by requiring prio
authorization (i.e., clinical pharmacist and/or Medical Director review) to ensure appropria
chronic non-cancer pain.

Description:

Opioid analgesics are classified as full agonists, mixed agonist-antagonists, or partial ago
opioid receptors in the central nervous system (CNS): mu, kappa, and delta. Mu-receptor
motility, and euphoria. Kappa-receptor activation also causes analgesia, but may also pr
use. Delta-receptor activation produces some analgesia but may also cause seizures at
agonists have activity at the mu, kappa, and delta receptors, but have the highest affinity
codeine, morphine), semisynthetic analogs (e.g., hydrocodone, hydromorphone, oxycodo
methadone, sufentanil, tapentadol, tramadol).

Morphine is the “gold standard” of pain management and is available in long acting and s
several dosage forms, covered under the pharmacy benefit, including oral and rectal.

Fentanyl is available in several dosage forms, covered under the pharmacy benefit, inclu
tablets and nasal spray. Fentanyl is indicated for breakthrough cancer pain in opioid toler

Oxycodone is available in immediate release and extended release formulations for the r
combination with acetaminophen, and to a lesser extent, ibuprofen or aspirin. A consider
exposure, so as not to exceed 4 grams of acetaminophen, 3.2 grams of ibuprofen or 4 gr
of aspirin daily.

There is no defined maximum dose for most opioids. The ceiling to analgesic effectivene
constipation, nausea and vomiting, dizziness, sedation, respiratory depression. Long-term
including but not limited to endocrinological effects, such as, hypogonadism, impotence i
induced hyperanalgesia caused by damage to the nociceptors thus increasing pain sens

When converting from one opioid to another or between different dosage forms, conversi
dosages, titration should be based on the individuals’ response. During titration, Morphin

(every 3-4 days for Avinza); oxycodone every 1 to 2 days, and fentanyl should not be titr
discontinuing long term medications, taper by 25-50% over several days to avoid withdra

Ideal treatment for persistent pain is a long-acting opioid administered around the clock,
doses should be equivalent to 10% of the total daily dose given every 1 to 2 hours. Conv
appropriate, when six to eight short acting doses daily is not providing sufficient pain reli
exceed the daily recommended dose of 4000mg.

Opioid Morphine Equivalent Conversion Factors

Type of Opioid	MME Conversion Facto
Buprenorphine patch	42
Buprenorphine tab or film	10
Butorphanol	7
Codeine	0.15
Dihydrocodeine	0.25
Fentanyl buccal or SL tablets, or lozenge/troche	0.13
Fentanyl film or oral spray	0.18
Fentanyl nasal spray	0.16
Fentanyl patch	7.2
Hydrocodone	1
Hydromorphone	4
Levorphanol tartrate	11
Meperidine hydrochloride	0.1
Methadone	3
Morphine	1
Nalbuphine	1
Opium	1
Oxycodone	1.5
Oxymorphone	3
Pentazocine	0.37
Tapentadol	0.4
Tramadol	0.1

Medication Safety Programs:

Morphine Extended Release, Oxycodone Hydrochloride Controlled-Release Tablet
requirements with transdermal products assigned to the ERLA Shared REMS, while tran

Program: This product is included in the shared Extended-Release and Long-Acting (EF
program includes a Medication Guide, Elements To Assure Safe Use (e.g., Dear Healthc
documents, risk assessment tool), and Assessments that must be submitted to the FDA.
opioidrems.com/IwgUI/rems/home.action, and the program phone number is 1-800-503-
http://www.er-la-opioidrems.com/IwgUI/rems/products.action and http://www.fda.gov/Dru

Purpose: To reduce the risk of serious adverse outcomes resulting from inappropriate p

patient access to pain medications. Potential adverse effects include addiction, unintentio

Prescriber Requirements: Prescribers are strongly encouraged to undergo the training
opioidrems.com/IwgUI/rems/training.action), and to counsel patients using the Patient Co
opioidrems.com/IwgUI/rems/pcd.action) and Medication Guide (http://www.er-la-opioidre
the ER/LA Shared REMS program (https://search.er-la-opioidrems.com/Guest/GuestPag

Pharmacy Requirements: Pharmacies are not required to enroll in the REMS program.
The most current Medication Guide for the prescribed product must be provided with eac

Medication Guide: FDA has required common opioid language within the Medication Gu
each contains product-specific risk information. Therefore, the appropriate and most curr
the patient and/or caregiver with each ER/LA opioid analgesic prescription dispensed by

**Fentanyl Sublingual Tablets, Fentanyl Oral Transmucosal Lozenges and Buccal Ta
FentanylSublingual Spray**

Program: Fentanyl products are subject to REMS requirements with transdermal produc
included in the TIRF Shared REMS. The FDA-approved transmucosal immediate-release
Element To Assure Safe Use that includes a restricted distribution system requiring preso
wholesalers/distributors. The program website is http://www.tirfremsaccess.com and the

Purpose: To mitigate the risk of misuse, abuse, addiction, overdose, and serious compli
and dispensed only to appropriate patients, including only those who are opioid-tolerant;
accidental drug exposure to children and others for whom the drug was not prescribed; a
abuse, addiction, and overdose.

Prescriber Requirements: Those who prescribe TIRF medicines for outpatient use are
who are already enrolled in an individual Risk Evaluation and Mitigation Strategy (REMS
they will be automatically transitioned to the shared TIRF REMS Access program. Recer
class REMS or from the date of enrollment into the individual REMS, whichever was earl
complete the knowledge assessment, and complete an enrollment form. Prescribers can
enrollment form to 1-866-822-1487. Additional information about the enrollment process
http://www.tirfremsaccess.com. Those who prescribe TIRF medicines only for inpatient u
enroll in the TIRF REMS Access program. Enrolled prescribers must provide a copy of th
TIRF REMS Patient-Prescriber Agreement. The patient should also sign the agreement.
copy to the patient/caregiver, and submit a copy within 10 working days via the program
Medication Guide for the new TIRF product must be provided, and reviewed with the pati

Pharmacy Requirements: All pharmacies must be enrolled in the TIRF REMS Access p
were previously enrolled in an individual TIRF REMS will not need to re-enroll because th
program. These pharmacies will have 6 months to agree to the shared program terms ar
dispensing privileges. Pharmacies will be required to re-enroll in the TIRF REMS progran
from the date of enrollment into the individual REMS, whichever was earlier. There is a d
mail order, institutional outpatient pharmacies that dispense for outpatient use) and inpat
dispense for inpatient use). Each inpatient and outpatient pharmacy is required to design
pharmacy. The designated authorized pharmacist must review the Education Program, s
enrollment form. Enrollment forms can be completed on the Web site or faxed (1-866-82
behalf of the pharmacy. The authorized pharmacist will then train other pharmacy staff in
Access program. Additional information about the enrollment process can be found on th
Chain pharmacies can enroll using the TIRF REMS Access program's Chain Pharmacy E

Dispensing Requirements (Patient enrollment): Prescribers are required to complete a
writing the patient's first outpatient prescription, and will review the Medication Guide with
The prescriber must retain a copy of the completed and signed agreement, provide a cop
program Web site or fax number. Patients will be enrolled in the TIRF REMS Access pro
prescription is filled. Patients can locate a participating pharmacy by consulting their pres

Medication Guide: The REMS program requires that a Medication Guide be dispensed

Monitoring Requirements (Lab tests): Prescribers are encouraged to perform careful pa
of misuse, abuse or addiction.

Documentation: Prescribers are required to maintain a copy of the completed and signe
to providing a copy to the patient, and submitting this document via the program Web site
process all TIRF medication prescriptions, regardless of method of payment, through the
weekly product activity data (i.e., EDI 867 transmission) to the TIRF REMS Access progr
compliance with the TIRF REMS Access program.

Other: Wholesalers/Distributors must enroll in the TIRF REMS Access program (http://w
thereafter. The Wholesaler/Distributor's authorized representative will review the TIRF R
Enrollment Form and send it to the TIRF Sponsors by fax (1-866-822-1487) or mail (TIRF
enrollment form each distributor is required to indicate they understand that TIRF medici
they must comply with program requirements. In signing the Distributor Enrollment Form
TIRF medicines are available only through the TIRF REMS Access program and acknow

Buprenorphine/Naloxone Sublingual

Program: The FDA-approved REMS program includes a Medication Guide, Elements to
Implementation System. More information is available at: http://www.suboxone.com/hcp/
http://www.zubsolvrems.com/ or by calling 1-877-ZUBSOLV (1-877-982-7658); and https
3922.

Purpose: To mitigate the risk of accidental overdose, misuse, and abuse and inform pre
containing products. REMS Programs are applicable when these products are prescribed
those patients admitted to an Opioid Treatment Program under 42 CFR Part 8.

Prescriber Requirements: Prescribers are encouraged to review REMS educational ma
counseling, dosing, and monitoring. Prescribers must be certified to treat opioid depende
to prescribe buprenorphine-containing products for maintenance treatment (http://www.zu
prescriber qualifications, notifying the Substance Abuse & Mental Health Services Admin
found at http://buprenorphine.samhsa.gov/, or by contacting SAMHSA directly. The SAM
(866-BUP-CSAT), and the email address is info@buprenorphine.samhsa.gov.

Pharmacy Requirements: Pharmacists are encouraged to read the Introductory Pharma
Brochure.

Dispensing Requirements (Patient enrollment): The REMS programs for buprenorphine-c

- Verify that the prescription received is in compliance with the provisions of DATA
- Keep in mind that a limited supply of buprenorphine-containing product should be
  physicians to closely and frequently assess the patients' needs, their symptoms a

- Provide the Medication Guide to patients each time the medicine is dispensed
- A limited amount of medication is prescribed at the first visit, after appropriate inc
- Advise patients to store buprenorphine-containing product in a safe place to prot
- Advise patients that unused doses of buprenorphine-containing product should b
- Be vigilant in detecting fraudulent prescriptions or simultaneous prescriptions for

Quantity Limits: No restrictions on prescription quantities are mandated by the REMS, b
treatment is initiated.

Medication Guide: The REMS program requires that a Medication Guide be dispensed

Monitoring Requirements (Lab tests): Prescribers must document that each patient ha
Checklist or by using another method/system (e.g., electronic health record) specific to th

Documentation: Prescribers are encouraged to monitor and document safe use conditio
and documentation, or to use another suitable office-specific alternative document. The A
(http://www.suboxone.com/hcp/pdfs/app_use_checklist.pdf; http://www.zubsolvrems.com
https://www.btodrems.com/Portal/Content%20Library/Appropriate%20Use%20Checklist.

Policy:

I. Transmucosal Immediate Release Fentanyl (TIRF) Products (applies to brand and

INITIAL REQUESTS

Fentanyl (Fentora ®, Onsolis™, Abstral®, Lazanda® and Subsys®) and fentanyl citrate (
met:

1. Use for breakthrough pain in members with cancer who are receiving long-acti
2. Member is 18 years of age or older (16 years of age and older for fentanyl citra
3. Tolerance to current opioid therapy (i.e., adherence to one of the following reg
   a. 25mcg of transdermal fentanyl hourly; or
   b. 30mg of oxycodone daily; or
   c. 60mg of oral morphine daily; or
   d. 8mg of oral hydromorphone daily; or
   e. 25mg of oral oxymorphone daily; or
   f. an equianalgesic dose of another opioid; and
4. For brand name products: inadequate response or inability to tolerate a generi

Authorization Length: 1 year

REAUTHORIZATION REQUESTS

Fentanyl and fentanyl citrate products are approved for reauthorization when BOTH of th

1. Continued use for breakthrough pain in members with cancer who are currentl
2. Documentation to support the efficacy associated with the current regimen (e.g

II. Opioids with abuse deterrent properties

INITIAL REQUESTS

Hydrocodone bitartrate (Zohydro ER™, Hysingla ER™ 20mg, 30mg, 40mg, 60mg, 80mg
1.2mg, 50mg-2mg is approved for members 18 years of age and older when ANY of the

1. Documentation of appropriate titration from a respective short-acting agent and
   medications:
   a. Morphine sulfate extended release; and
   b. Oxycodone extended release; or
2. Documentation of risk of abuse potential from the appropriate specialist with a c

REAUTHORIZATION REQUESTS

Hydrocodone bitartrate (Zohydro ER™, Hysingla ER™ 20mg, 30mg, 40mg, 60mg, 80mg
1.2mg, 50mg-2mg is approved for reauthorization for members 18 years of age and olde

1. Documentation of current patient-prescriber opioid treatment agreement from ap
   associated with the current regimen (e.g. pain scores, clinical response); or
2. Documentation of risk of abuse potential from the appropriate specialist with a cu

Authorization duration: 1 year

III. High Dose Narcotics (applies to brand and generic products)

INITIAL CRITERIA [Authorization Length: 1 year]

The requested high dose product or regimen is considered medically necessary when th

1. Pain associated with a cancer diagnosis and member is undergoing active treat
2. Severe, persistent chronic pain with ALL of the following:
   a. Physical exam to assess underlying etiology; and
   b. Documentation of one of the following:
      i. Regimen prescribed by a Pain Management Specialist; or
         1. Must provide name of physician and date of last visit (must
         2. Physician must be Board Certified by one of the following:
            a. American Board of Anesthesiology- Pain Manageme
            b. American Board of Psychiatry & Neurology- Pain Ma
            c. American Board of Physical Medicine & Rehabilitatio
            d. American Osteopathic Association- Pain Manageme
      ii. Appropriate concurrent therapy consisting of at least two of the fo
         1. Physical therapy; or
         2. Psychotherapy; or
         3. Adjuvant medications specific to causative condition includin
            a. Antidepressants
            b. Anticonvulsants
            c. Muscle relaxants
            d. Anti-inflammatory agents; and
   c. Documentation of narcotic treatment history including the following:
      i. Titration history for the last 6 months; and
      ii. Optimization of long-acting narcotics with appropriate utilization
   d. Documentation of a current patient-prescriber opioid treatment agreem

Authorization Length: 1 year

CONTINUATION CRITERIA

The requested high dose product or regimen will be re-authorized when ONE of the follo

1. Member is either actively receiving cancer treatment or is not in remission; reau
2. For severe, persistent chronic pain or residual pain associated with cancer trea documentation of ALL of the following:
    a. Urine drug screen (UDS) is performed at least annually by prescriber; a
    b. Current patient-prescriber opioid treatment agreement; and
    c. either of the following:
        i. Regimen prescribed by a pain management specialist (as defined
        ii. Documentation of appropriate concurrent therapy (as defined in th
3. Planned discontinuation or titration down of therapy, re-authorization length is 6

IV. Appropriate Utilization with Abuse Deterrents

Narcotics analgesics will require prior authorization for medical necessity when fi (Bunavail®/Suboxone®/Zubsolv®) or **buprenorphine** (Subutex®).

Narcotic analgesic products are approved in patients that have received buprenorphine/n documentation of a treatment plan showing discontinuation of causative product (bupren

V. Duplicate therapy/Class quantity limits

1. Initial requests: Duplicate opioid requests are approved when ALL of the following
    a. Appropriate diagnosis upon visit with a qualified specialist for diagnosis
    b. Insufficient response to previous treatments; and
    c. Need for more than one long acting or more than one short acting conc
    d. The requested dose does not exceed FDA or accepted clinical dosing g
    e. ONE of the following:
        i. Intolerance or contraindication to higher doses of a single opioid;
        ii. Dose requested does not exist as a single tablet form
2. Reauthorization requests: Duplicate opioid requests are reapproved when ALL
    a. Appropriate diagnosis upon visit with a qualified specialist for diagnosis
    b. Need for more than one long acting or more than one short acting conc be documented); and
    c. The requested dose does not exceed FDA or accepted clinical dosing g
    d. One of the following:
        i. Intolerance or contraindication to higher doses of a single opioid;
        ii. Dose requested does not exist as a single tablet form; and
    e. Documentation to support the efficacy associated with the current regim

Black Box Warning:

TIRFs (Abstral®, Actiq®, Fentora®, Onsolis™, Subsys®)

Respiratory depression:

Fatal respiratory depression has occurred in patients treated with fentanyl transmucosal patients and improper dosing. The substitution of fentanyl sublingual/buccal for any other
Because of the risk of respiratory depression, fentanyl sublingual/buccal is contraindicate headache/migraine and in opioid-intolerant patients.
Death has been reported in children who have accidentally ingested fentanyl transmucos children.
The concomitant use of fentanyl sublingual with CYP3A4 inhibitors may result in an incre respiratory depression.

Medication errors:

Substantial differences exist in the pharmacokinetic profile of fentanyl sublingual/buccal c

differences in the extent of absorption of fentanyl that could result in fatal overdose.
When prescribing, do not convert patients on a mcg-per-mcg basis from any other fentar
When dispensing, do not substitute a fentanyl sublingual/buccal prescription for other fer

Abuse potential:
Fentanyl is an opioid agonist and a Schedule II controlled substance, with an abuse liabi
similar to other opioid agonists, legal or illicit. This should be considered when prescribin
concerned about an increased risk of misuse, abuse, or diversion.
Because of the risk for misuse, abuse, addiction, and overdose, fentanyl sublingual/bucc
Drug Administration, called a Risk Evaluation and Mitigation Strategy (REMS). Under the
Program, outpatients, health care providers who prescribe to outpatients, pharmacies, ar
http://www.TIRFREMSaccess.com or by calling 1-866-822-1483.

Duragesic®

Addiction, abuse, and misuse: Fentanyl exposes patients and other users to the risks of
Assess each patient's risk prior to prescribing fentanyl, and monitor all patients regularly

Life-threatening respiratory depression: Serious, life-threatening, or fatal respiratory depr
Monitor for respiratory depression, especially during initiation of fentanyl or following a do
contraindicated for use as an as-needed analgesic, in nonopioid tolerant patients, in acut

Accidental exposure: Deaths due to a fatal overdose of fentanyl have occurred when chil
the recommended handling and disposal instructions is of the utmost importance to prev

Neonatal opioid withdrawal syndrome: Prolonged use of fentanyl during pregnancy can r
if not recognized and treated, and requires management according to protocols develope
a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome

Cytochrome P450 3A4 interaction: The concomitant use of fentanyl with all cytochrome P
concentrations, which could increase or prolong adverse drug effects and may cause pot
concomitantly used cytochrome P450 3A4 inducer may result in an increase in fentanyl p
inhibitor.

Exposure to heat: Exposure of the fentanyl application site and surrounding area to direc
tanning lamps, sunbathing, hot baths, saunas, hot tubs, and heated water beds may incr
death. Patients wearing fentanyl systems who develop fever or increased core body temp
exposure and may require an adjustment in the dose of fentanyl to avoid overdose and d

Lazanda®

Respiratory depression:
Fatal respiratory depression has occurred in patients treated with fentanyl transmucosal
and improper dosing. The substitution of fentanyl intranasal for any other fentanyl produc
Because of the risk of respiratory depression, fentanyl intranasal is contraindicated in the
and in opioid non-tolerant patients.
Fentanyl intranasal must be kept out of the reach of children.
The concomitant use of fentanyl intranasal with CYP3A4 inhibitors may result in an incre
respiratory depression.[1]

Medication errors:
Substantial differences exist in the pharmacokinetic profile of fentanyl intranasal compare
in the extent of absorption of fentanyl that could result in fatal overdose.
When prescribing, do not convert patients on a mcg-per-mcg basis from any other fentar

When dispensing, do not substitute a fentanyl intranasal prescription for other fentanyl pr

Abuse potential:
Fentanyl is an opioid agonist and a Schedule II controlled substance, with an abuse liabi
a manner similar to other opioid agonists, legal or illicit. Consider this when prescribing o
provider or pharmacist is concerned about an increased risk of misuse, abuse, or diversi
Because of the risk for misuse, abuse, addiction, and overdose, fentanyl intranasal is ava
Administration, called a Risk Evaluation and Mitigation Strategy (REMS). Under the Tran
outpatients, health care providers who prescribe to outpatients, pharmacies, and distribu
http://www.TIRFREMSAccess.com or by calling 1-866-822-1483.

Butrans®

Addiction, abuse, and misuse: Buprenorphine exposes patients and other users to the ris
death. Assess each patient's risk prior to prescribing buprenorphine and monitor all patie

Life-threatening respiratory depression: Serious, life-threatening, or fatal respiratory depr
depression, especially during initiation of buprenorphine or following a dose increase. Mi
injecting buprenorphine extracted from the transdermal system will result in the uncontro
death.

Accidental exposure: Accidental exposure to even one dose of buprenorphine, especially

Neonatal opioid withdrawal syndrome: Prolonged use of buprenorphine during pregnanc
threatening if not recognized and treated, and requires management according to protoc
prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid w

Hydromorphone (Dilaudid, Exalgo®)

Hydromorphone immediate release: Hydromorphone is a potent Schedule II controlled op
abuse and risk of producing respiratory depression. Alcohol, other opioids, and CNS dep
of hydromorphone, increasing the risk of respiratory depression that might result in death

Hydromorphone extended release:
Addiction, abuse, and misuse**:** Hydromorphone extended release (ER) exposes patients
can lead to overdose and death. Assess each patient's risk prior to prescribing hydromor
behaviors or conditions.

Life-threatening respiratory depression: Serious, life-threatening, or fatal respiratory depr
depression, especially during initiation of hydromorphone ER or following a dose increas
chewing, or dissolving tablets can cause rapid release and absorption of a potentially fata

Accidental ingestion: Accidental ingestion of even 1 dose, especially in children, can resu

Neonatal opioid withdrawal syndrome: Prolonged use during pregnancy can result in neo
recognized and treated, and requires management according to protocols developed by
pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome a

Methadone

Addiction, abuse, and misuse: Methadone exposes patients and other users to the risks
death. Assess each patient's risk prior to prescribing methadone, and monitor all patients

Life-threatening respiratory depression: Serious, life-threatening, or fatal respiratory depr
depression, especially during initiation of methadone or following a dose increase.

Life-threatening QT prolongation: QT interval prolongation and serious arrhythmia (torsa
cases involve patients being treated for pain with large, multiple daily doses of methadon
commonly used for maintenance treatment of opioid addiction. Closely monitor patients f

Neonatal opioid withdrawal syndrome: Prolonged use of methadone during pregnancy ca
threatening if not recognized and treated, and requires management according to protoc
prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid w

Accidental ingestion: Accidental ingestion of even one dose of methadone, especially by

Treatment of opioid addiction: For detoxification and maintenance of opioid dependence,
standards cited in 42 CFR Section 8, including limitations on unsupervised administratio

Morphine Sulfate

Avinza® and Kadian®:
Interaction with alcohol: Instruct patients not to consume alcoholic beverages or use pres
morphine extended-release (ER) capsules. The co-ingestion of alcohol with morphine m
morphine.

Avinza®, Kadian®, and MS Contin®:
Addiction, abuse, and misuse: Morphine ER exposes patients and other users to the risk
death. Assess each patient's risk prior to prescribing morphine ER and monitor all patien

Life-threatening respiratory depression: Serious, life-threatening, or fatal respiratory dep
depression, especially during initiation of morphine or following a dose increase. Instruct
contents may be sprinkled on applesauce and swallowed without chewing. Crushing, ch
rapid release and absorption of a potentially fatal dose of morphine.

Neonatal opioid withdrawal syndrome: Prolonged use of morphine during pregnancy can
threatening if not recognized and treated, and requires management according to protoc
prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid w

Accidental ingestion: Accidental ingestion of even 1 dose of morphine, especially by chil

Oral solution:
Morphine oral solution is available in 10 mg per 5 mL, 20 mg per 5 mL, and 100 mg per

The 100 mg per 5 mL (20 mg/mL) concentration is indicated for use in opioid-tolerant pa

Take care when prescribing and administering morphine oral solution to avoid dosing err
milligrams and milliliters, which could result in accidental overdose and death. Take care

Keep morphine oral solution out of the reach of children. In case of accidental ingestion,

Nucynta ER®/ Opana ER®

Addiction, abuse, and misuse: Tapentadol ER/Oxymorphone ER exposes patients and o
lead to overdose and death. Assess each patient's risk prior to prescribing tapentadol E
these behaviors or conditions.

Life-threatening respiratory depression: Serious, life-threatening, or fatal respiratory dep
respiratory depression, especially during initiation of tapentadol ER/oxymorphone ER or
ER/oxymorphone ER tablets whole; crushing, dissolving, or chewing tapentadol ER/oxy
dose of tapentadol ER/oxymorphone ER.

Accidental ingestion: Accidental ingestion of even 1 dose of tapentadol ER/oxymorphone
tapentadol/oxymorphone.

Neonatal opioid withdrawal syndrome: Prolonged use of tapentadol ER/oxymorphone ER
which may be life-threatening if not recognized and treated, and requires management a
required for a prolonged period in a pregnant woman, advise the patient of the risk of neo
will be available.

Interaction with alcohol: Patients must not consume alcoholic beverages or take prescrip
tapentadol ER/oxymorphone ER. The co-ingestion of alcohol with tapentadol ER/oxymor
and a potentially fatal overdose of tapentadol/oxymorphone.

Oxycodone (Oxycontin®, oxycodone concentrate)

Addiction, abuse, and misuse: Oxycodone extended release (ER) exposes patients and o
lead to overdose and death. Assess each patient's risk prior to prescribing oxycodone an
conditions.

Life-threatening respiratory depression: Serious, life-threatening, or fatal respiratory depr
depression, especially during initiation of oxycodone ER or following a dose increase. Ins
or chewing the tablet can cause rapid release and absorption of a potentially fatal dose o

Accidental ingestion: Accidental ingestion of even one dose of oxycodone ER, especially

Neonatal opioid withdrawal syndrome: Prolonged use of oxycodone ER during pregnanc
threatening if not recognized and treated and requires management according to protoco
prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid w

Cytochrome P450 3A4 interaction: The concomitant use of oxycodone ER with all cytoch
concentrations, which could increase or prolong adverse drug effects and may cause pot
concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodon
CYP3A4 inhibitor or inducer.

Concentrated oral solution:
Oxycodone concentrated oral solution is available as a 20 mg/mL concentration and is in

Take care when prescribing and administering oxycodone concentrated oral solution to a
other oxycodone solutions with different concentrations, which could result in accidental o
and dispensed. Keep oxycodone out of the reach of children. In case of accidental inges

Zohydro ER™

Addiction potential: Hydrocodone ER exposes patients and other users to the risks of opi
Assess each patient's risk prior to prescribing, and monitor all patients regularly for the d

Life-threatening respiratory depression: Serious, life-threatening, or fatal respiratory depr
depression, especially during initiation or following a dose increase. Instruct patients to s
capsules can cause rapid release and absorption of a potentially fatal dose of hydrocodo

Accidental exposure: Accidental consumption of even 1 dose of hydrocodone ER, espec

Neonatal opioid withdrawal syndrome: Prolonged maternal use of hydrocodone ER durin
be life-threatening if not recognized and treated, and requires management according to
prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid w

Interaction with alcohol: Instruct patients not to consume alcoholic beverages or use pres
hydrocodone. The co-ingestion of alcohol with hydrocodone may result in increased plas

Cytochrome P450 3A4 interaction: The concomitant use of hydrocodone ER with all cyto
hydrocodone plasma concentrations, which could increase or prolong adverse drug effec
discontinuation of a concomitantly used CYP3A4 inducer may result in an increase in hy
ER and any CYP3A4 inhibitor or inducer.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosag

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug
the Company's products when the medical necessity criteria listed in this pharmacy polic
are benefit contract exclusions for all products of the Company.

References:

Chou R, Franciullo GJ, Fine PG, et al; and the American Pain Society-American Academ
Clinical Guidelines for the Use of Opioid Therapy in Chronic Noncancer Pain. J Pain 10:

Franklin, Gary M. Opioids for chronic noncancer pain: A position paper of the American

Tennant, Forest. Critical Transition from Short-to-Long Acting Opioid Therapy. Novembe
http://www.practicalpainmanagement.com/treatments/pharmacological/opioids/critical-tra

Centers for Medicare and Medicaid Services. Opioid Morphine Equivalent Conversion Fa
Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Fact

Product Information: ONSOLIS(TM) buccal, soluble film, fentanyl buccal, soluble film. Bi
June 5, 2015.

Lazanda [package insert]. Bedminster NJ. Archimedes Pharma US Inc. 2011. Revised 0

Micromedex website [Exalgo]. Available at www.micromedex.com. Accessed June 5, 20

American Board of Anesthesiology- Pain Management: http://directory.theaba.org/defaul

American Board of Psychiatry & Neurology- Pain Management: https://application.abpn.

American Board of Physical Medicine & Rehabilitation- Pain Management: https://www.a

American Osteopathic Association- Pain Management: http://www.osteopathic.org/Page

Avinza (morphine) Medication Guide. Available at
http://www.fda.gov/downloads/Drugs/DrugSafety/UCM311346.pdf. Accessed June 5, 20

Kadian (morphine sulfate) Medication Guide. Available at http://www.fda.gov/downloads/

Morphine ER Capsules - Actavis Medication Guide. Available at http://pi.actavis.com/dat
June 5, 2015.
Morphine ER Tablets - Mallinckrodt Medication Guide. Available at http://www2.mallinck
5, 2015.

Morphine Oral Solution - Lannett Medication Guide. Available at http://www.lannett.com/

Accessed June 5, 2015

Morphine Oral Solution - Mallinckrodt Medication Guide. Available at http://www2.mallinc
2015.

Morphine Oral Solution - Roxane Medication Guide. Available at http://www.fda.gov/dow

Morphine Sulfate ER Capsules - Upsher-Smith Medication Guide. Available at http://www
June 5, 2015.

Morphine Sulfate ER Tablets - Mylan Medication Guide. Morphine Sulfate ER Tablets- M
http://medlibrary.org/lib/rx/meds/morphine-sulfate-41. Accessed June 5, 2015.

Morphine Sulfate ER Tablets - Rhodes Medication Guide. Available at
http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=19c7d9cc-6ce2-4c5c-8c3f-c24f

Morphine Sulfate Oral Solution - VistaPharm Medication Guide. Available at
http://medlibrary.org/lib/rx/meds/morphine-sulfate-25/. Accessed June 5, 2015.

MS Contin (morphine sulfate) Medication Guide. Available at http://www.fda.gov/downloa

Oxycodone Oral Solution - VistaPharm Medication Guide. Available at http://online.factsa

Oxycodone Oral Solution - Glenmark Medication Guide. Available at
http://online.factsandcomparisons.com/MedGuide/585993.pdf. Accessed June 5, 2015.

Oxycodone Oral Solution - Midlothian Medication Guide. Available at http://online.factsan

Oxycodone Oral Solution - Roxane Medication Guide. Available at http://online.factsandc

Duragesic (fentanyl) Medication Guide. Available at http://www.fda.gov/downloads/Drugs

Fentanyl TD Patch - Novaplus Medication Guide. Available at http://www.medicationdaily

Fentanyl Transdermal Patch - Par Medication Guide. Available at http://dailymed.nlm.nih
2e33196faca0. Accessed June 5, 2015.

Fentanyl Transdermal Patch - Upsher-Smith Medication Guide. Available at http://www.u
2015.

Fentanyl Transdermal System - Actavis Medication Guide. Available at http://pi.actavis.c
Accessed June 5, 2015.

Fentanyl Transdermal System - Apotex Medication Guide. Available at https://www.apote
2015.

Fentanyl Transdermal System - Mallinckrodt Medication Guide. Available at http://www2.
5, 2015.

Fentanyl Transdermal System - Sandoz Medication Guide. Available at http://dailymed.n
6398f4d467b3. Accessed June 5, 2015.

Buprenorphine/Naloxone Sublingual Tablets - Actavis Medication Guide. Available at
http://pi.actavis.com/data_stream.asp?product_group=1853&p=medguide&language=E.

Buprenorphine/Naloxone Sublingual Tablets - Amneal Medication Guide. Available at http://online.factsandcomparisons.com/MedGuide/607240.pdf. Accessed June 5, 2015.

Suboxone (buprenorphine/naloxone) Medication Guide. Available at https://www.suboxo

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/re

I. Transmucosal Immediate Release Fentanyl (

Brand name	Generic name
Abstral	Fentanyl sublingual tab
Actiq	Fentanyl buccal lollipop
Fentora	Fentanyl buccal tablet
Lazanda	Fentanyl nasal solution
Onsolis	Fentanyl buccal soluble
Subsys	Fentanyl sublingual liqu

II. Opioids with abuse deterrent prope

Brand name	Generic name
Zohydro ER	Hydrocodone bitartra
Hysingla ER 20mg, 30mg, 40mg, 60mg, 80mg, 100mg	Hydrocodone bitartra
Embeda 20mg-0.8mg, 30mg-1.2mg, 50mg-2mg	Morphine sulfate/nal

III. High Dose Narcotic Analgesics

Brand Name	Generic Name	
Avinza	Morphine sulfate extended release capsule 24HR	1
Dilaudid	Hydromorphone immediate release	4
Duragesic patch	Fentanyl transdermal patch 72 HR	2
Embeda	Morphine sulfate/naltrexone	6
Exalgo	Hydromorphone tablet extended release 24HR Abuse deterrent	8
Hysingla ER	Hydrocodone ER	1
Kadian	Morphine sulfate extended release 24HR capsule	6
Various (e.g. Methadose)	Methadone	A
Morphine sulfate tablet	Morphine sulfate tablet	3
MS Contin	Morphine sulfate extended release tablet	6
Nucynta	Tapendatol immediate release	1
Nucynta ER	Tapendatol extended release	1
Opana	Oxymorphone	1
Opana ER	Oxymorphone	2
Oxy IR	Oxycodone immediate release	3
Oxycontin	Oxycodone extended release	3

IV. Appropriate utilization with abuse de

Brand name	Ge
Abstral/Actiq/Fentora/Lazanda/Subsys/Onsolis	Fentanyl imme
Avinza	Morphine sulfa

Butrans patch	Buprenorphine
Capital/Codeine	APAP/Codeine
Codeine sulfate	Codeine sulfat
Conzip	Tramadol ER c
Demerol/Meperitab	Meperidine HC
Dilaudid	Hydromorphon
Duragesic patch	Fentanyl transd
Embeda	Morphine sulfa
Endocet/Percocet/Primlev	Oxycodone/ac
Endodan/Percodan	Oxycodone/asp
Exalgo	Hydromorphon tablet
Hycet	Hydrocodone/a
Hydromorphone oral solution	Hydromorphon
Kadian	Morphine sulfa
Levorphanol tartrate tablets	Levorphanol ta
Meperidine oral solution	Meperidine liqu
Methadose/Diskets	Methadone
Morphine sulfate concentrate/oral solution/tablets	Morphine
MS Contin	Morphine sulfa
Norco/Lortab/Vicodin	Hydrocodone/a
Nucynta	Tapentadol
Nycynta ER	Tapentadol ER
Opana	Oxymorphone
Opana ER	Oxymorphone
Oxy IR/Roxicodone	Oxycodone HC
Oxycodone	Oxycodone sol
Oxycontin tablets	Oxycodone HC
Roxicet	Oxycodone/ac
Tylenol #3/Tylenol #4	Acetaminophen
Ultracet	Tramadol/aceta
Ultram	Tramadol
Ultram ER	Tramadol ER
Vicoprofen	Hydrocodone/i
Xartemis XR	Oxycodone/ac
Zohydro ER/Hysingla ER	Hydrocodone b

Cross References:

Buprenorphine and Naloxone (Suboxone, Zubsolv, Bunavail) and Buprenorphine (Subutex). Policy # Rx.01.7
Controlled Substance Quantity Limits. Policy # Rx.01.16

Experimental/Investigational Use. Policy # Rx.01.33

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