Pharmacy Policy Bulletin

Title:	Opioid Policy
Policy #:	Rx.01.197

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria including prior authorization, quantity limits, and days' supply for opioid analgesics, buprenorphine containing medication assistant treatments, and butalbital containing headache medications as provided under the member's prescription benefit.

Description:

Opioid analgesics are classified as full agonists, mixed agonist-antagonists, or partial agonists by their activity at opioid receptors. There are three major classes of opioid receptors in the central nervous system (CNS): mu, kappa, and delta. Mu-receptor activation causes analgesia, respiratory depression, miosis, reduced GI motility, and euphoria. Kappa-receptor activation also causes analgesia, but may also produce effects such as dysphoria and hallucinations, which limit use. Delta-receptor activation produces some analgesia but may also cause seizures at high doses and has some antidepressant effects. Morphine-like opioid agonists have activity at the mu, kappa, and delta receptors, but have the highest affinity for the mu receptors[1]. Opioid agonists include natural opium alkaloids (e.g., codeine, morphine), semisynthetic analogs (e.g., hydrocodone, hydromorphone, oxycodone, oxymorphone), and synthetic compounds (e.g., fentanyl, levorphanol, methadone, sufentanil, tapentadol, tramadol). There is no defined maximum dose for most opioids. The ceiling to analgesic effectiveness is imposed only by adverse reactions. Adverse effects of opioids include constipation, nausea and vomiting, dizziness, sedation, respiratory depression[2]. Long-term use of high dose narcotics may also have significant adverse effects including but not limited to endocrinological effects, such as, hypogonadism, impotence in males, menstrual irregularities, and galactorrhea in women; and opioid induced hyperanalgesia caused by damage to the nociceptors thus increasing pain sensitivity[3].

Opioid analgesics are commonly prescribed in pain management. Pain is classified into non-cancer and cancer related pain. Non-cancer related pain may be acute or chronic while cancer-related pain may be a

mixture of both[2]. When using opioid agents to manage pain, the choice should be made based on patient acceptance, pain intensity, analgesic effectiveness, pharmacodynamic, pharmacokinetic and side effect profiles. Like the treatment of many disease states, pain treatment should be initiated with the most effective agent with minimal side effects. Prior to starting patient on opioid pain management, pain severity and intensity should be thoroughly assessed using patient medical history, physical examination and different pain assessment tools like NRS, VAS, and FPS[4]. In the management of mild non-cancer pain, the American Pain Society recommends the use of non-opioid analgesics such as acetaminophen and NSAIDs as first line agents. If pain relief is not adequate, opioid analgesics could be considered as the next line of treatment. Combination treatments of opioid with acetaminophen or NSAIDs are recommended when treating moderate to severe non-cancer pain. Common opioid analgesics like oxycodone and hydrocodone are often co-formulated with acetaminophen or NSAIDs and have a maximum dose to limit the amount of acetaminophen and NSAIDs exposure. It is recommended not to exceed 4000 mg of acetaminophen per day or 1000 mg every 4 to 6 hours, 3.2 grams of ibuprofen or 4 grams (3.9 grams for controlled-, extended-, and delayed-release products) of aspirin daily.

Pain that is associated with cancer or a malignant condition is known as cancer related pain. Cancer related pain may be acute and/or chronic. Pain related to cancer is usually the result of damage to parts of the body from cancer metastasis or therapies such as chemotherapy, radiation and surgical procedures. Opioid analgesics play an important role in pain management for oncology patients. The World Health Organization developed a pain relief regimen known as the WHO's Pain Relief Ladder which provides guidelines for pain management in cancer patients[5]. Like non-cancer related pain, opioid analgesics are reserved for moderate to severe cancer pain. Patients with mild pain should try non-opioid analgesics such as acetaminophen, ibuprofen, or naproxen first. Opioid agents or opioid combination are reserved for moderate to severe cancer pain or when inadequate pain relief is not achieved with non-opioid analgesics.

Morphine is considered to be the prototype or the "gold standard" of pain management. It is available in long acting (extended release) and short acting (immediate release) formulations in several dosage forms that are covered under the pharmacy benefit, including oral and rectal. Fentanyl is indicated for breakthrough cancer pain in opioid tolerant patients. Fentanyl is also available in several dosage forms, covered under the pharmacy benefit, including transdermal patch, buccal lollipops and tablets, sublingual liquid, tablets and nasal spray. Oxycodone is a common opioid semisynthetic analog that is available in immediate and extended release formulations for the management of acute and chronic pain. Oxycodone is frequently used in combination with acetaminophen, and to a lesser extent, ibuprofen or aspirin. The ceiling to analgesic effectiveness is imposed only by adverse reactions such as constipation, nausea and vomiting, dizziness, sedation, and respiratory depression. Higher doses of opioids along with other factors are associated with increased risk of opioid overdose. To minimize this risk, utilization tools including quantity limits are designed to limit the daily dose of opioids to 90 mg morphine equivalent dose (MED), the number that is used to determine and compare the potency of opioid medications. The threshold of 90 MED is based on the recommendations from the Centers for Disease Control and Prevention: "When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day." When converting from one opioid to another or between different dosage forms, conversion factors should be used to assure equianalgesic dosing. When increasing dosages, titration should be based on the individuals' response. During titration, oxycodone and Morphine ER doses should not be titrated more frequently than every 1-2 days (every 3-4 days for Avinza). Fentanyl should not be titrated more frequently than every 3 days. When decreasing doses or discontinuing long term medications, taper by 25-50% over several days to prevent withdrawal[11]. Ideal treatment for persistent pain is a long-acting opioid administered around the clock, with the use of short-acting opioids for breakthrough pain. Breakthrough doses should be equivalent to 10% of the total daily dose given every 1 to 2 hours as needed. Conversion from a short acting to a long acting opioid should be considered, if appropriate, when six to eight short acting doses daily is not providing sufficient pain

relief, or when acetaminophen doses in combination products is likely to exceed the daily recommended dose of 4000mg[11].

The use of butalbital containing products in tension-type headache

Butalbital is a barbiturate that is commonly prescribed in combination with acetaminophen and caffeine to treat different types of headaches such as tension-type and migraines. It works by decreasing motor activity and depress the sensory cortex causing CNS depression ranging from sedation to general anesthesia[6]. The analgesia effect of barbiturate is unknown. However, there are limited studies that show the efficacy of butalbital in the treatment of tension type headache and migraine[7]. In addition, overuse of barbiturate products could lead to dependency, withdrawal, and drug-induced headache. Therefore, when selecting a treatment for tension-type headache as well as other types of headaches, butalbital containing products should be only be used if first line analgesics like acetaminophen or NSAIDs provide insufficient relief. In acute management, butalbital products should not be used more than 3 days[7].

Morphine Milligram Equivalent (MME) Conversion Factors for Commonly Prescribed Opioid Analgesics[12]

Opioids	Conversion Factors
Codeine	0.15
Fentanyl Transdermal	2.4
Hydrocodone	1
Hydromorphone	4
Methadone (mg/d) 1-20 21-40 41-60 ≥67-80	 4 8 10 12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol	0.4

Days' Supply and Quantity limits

Quantity limits are designed to allow a sufficient supply of medication based upon FDA-approved or medically accepted maximum daily doses and length of therapy of a particular drug. While opioid doses are variable and may have no true maximum, quantity limits are in place to address safety concerns, including abuse, addiction, and diversion. The limits in this policy restrict quantities to either the daily

MED of 90 mg or the FDA limit of additional product components such as 4 grams of acetaminophen, 3.2 grams of ibuprofen or 4 grams of aspirin. Quantity limits may be expressed as quantity over time or maximum daily dose. Additionally, there are some medications to which a limit on the days' supply is applied.

A. **Quantity over time:** This quantity limit is based on dosing guidelines over a rolling time period, usually 30 days.
B. **Maximum daily dose** (maximum quantity per day): This quantity limit is based on maximum number of units of the drug allowed per day.
C. **Days' supply limit:** This limits the numbers of days of therapy in a defined time period. Maximum daily dose applies to days' supply limits.

Policy:

PRIOR AUTHORIZATION

I. Transmucosal Immediate Release Fentanyl (TIRF) Products [Fentanyl (Fentora ®, Onsolis™, Abstral®, Lazanda® and Subsys®) and fentanyl citrate (Actiq®)] – are considered medically necessary when:

A. INITIAL CRITERIA [Authorization Length: 1 year]: Transmucosal Immediate Release Fentanyl (TIRF) Products are considered medically necessary when there is documentation of ALL of the following:

a. Use for breakthrough pain associated with active cancer treatment or cancer not in remission in members who are receiving long-acting opioid therapy; and
b. Member is 18 years of age or older (16 years of age and older for fentanyl citrate); and
c. Member is tolerant to current opioid therapy (i.e., adherence to one of the following regimens for one week or longer: 25mcg of transdermal fentanyl hourly, 30mg of oxycodone daily, 60mg of oral morphine daily, 8mg of oral hydromorphone daily, 25mg of oral oxymorphone daily; or an equianalgesic dose of another opioid); and
d. For BRAND name products: inadequate response or inability to tolerate a generic oral transmucosal fentanyl citrate product for at least one week.

B. REAUTHORIZATION CRITERIA [Authorization Length: 1 year]: Transmucosal Immediate Release Fentanyl (TIRF) products are re-approved when there is documentation of continued use for breakthrough pain associated with active cancer treatment or cancer not in remission in members who are currently receiving long-acting opioid therapy

II. High Dose Opioids and low dose opioids for continuation beyond 30days [Authorization Length: 1 year] - The requested high dose product or regimen is considered medically necessary when there is ONE of the following:

2. Pain associated with active cancer treatment, cancer not in remission, or sickle cell anemia OR
3. Severe, persistent chronic pain with documentation of diagnosis associated with pain and ALL of the following:

i. Documentation of a current patient-prescriber opioid treatment agreement (signed within one year of request); and
ii. ONE of the following

1. Regimen prescribed by or in consultation with a pain management specialist within last 6 months. Must provide name of physician and date of last visit. Physician must be Board Certified by one of the following:
    a. American Board of Anesthesiology- Pain Management; or
    b. American Board of Psychiatry & Neurology- Pain Management; or
    c. American Board of Physical Medicine & Rehabilitation; or
    d. American Osteopathic Association- Pain Management

    OR

2. The prescriber has completed BOTH of the following
    a. Evaluated the member for at least TWO of the following therapies:
        i. Physical therapy; or
        ii. Psychotherapy; or
        iii. Adjuvant medications specific to causative condition including but not limited to any of the following: antidepressants, anticonvulsants, muscle relaxants, anti-inflammatory agents;

        AND

    b. Provided documentation of appropriate opioid dose titration history
3. ADDITIONAL CRITERIA if continuation of therapy: documentation of a urine drug screen (UDS) performed by prescriber within 1 year of request.

3. ADDITIONAL CRITIERIA for BRAND drugs with generic equivalent: Documentation of adequate response or inability to tolerate the generic equivalent

4. ADDITIONAL CRITIERIA for Opioids with abuse deterrent properties (see list): Documentation of Inadequate response or inability to tolerate two generic opioid analgesics or documentation of a history of or a potential for drug abuse for individual or a member of the individual's household

III. Appropriate Utilization with Medication Assistant Treatments (MAT) for opioid use disorder - [Authorization Length: 2 months] - Opioid analgesics will require prior authorization for medical necessity when filled within two months of a paid claim for either buprenorphine/naloxone (Bunavail®/Suboxone®/Zubsolv®) or buprenorphine (Subutex®). Opioid analgesic products are approved in patients that have received buprenorphine/naloxone or buprenorphine in the previous two months when there is documentation of a treatment plan showing discontinuation of buprenorphine containing MAT.

DAYS' SUPPLY AND QUANTITY LIMITS

Day supply limit Criteria

A. Low Dose Opioids short term use (greater than two 5-day fills within 60 days) [Authorization Length: 30 days, 30 days' supply] - an exception is approved when ALL of the following are met:

1. **INITIAL CRITERIA**

4. Diagnosis of acute pain; and
5. Prescriber reviewed member's history in state Prescription Drug Monitoring Program website; and
6. Prescriber counseled member (or member's representative) on risk of addiction; and
7. Substance abuse screening done by prescriber
8. ADDITIONAL CRITIERIA for BRAND drugs with generic equivalent: Documentation of adequate response or inability to tolerate the generic equivalent
9. ADDITIONAL CRITIERIA for opioids with abuse deterrent properties (see list): Documentation of inadequate response or inability to tolerate two generic opioid analgesics or documentation of a history of or a potential for drug abuse for the individual or a member of the individual's household

2. **REAUTHORIZATION CRITERIA** see high dose /long-term use criteria under II

B. Opioid containing cough and cold products are limited to a five (5) day supply - an exception is approved when

1. INITIAL CRITERIA: there is documentation of inadequate response or inability to tolerate non-opioid therapies for the indication [Authorization duration 1 month]

2. REAUTHORIZATION CRITERIA: Documentation of BOTH of the following

a. Inadequate response or inability to tolerate non-opioid therapies for the indication; and

b. The underlying etiology of cough has been identified and treated, if applicable (eg allergic rhinitis, asthma, GERD) [Authorization duration 6 months]

C. Butalbital containing headache products [Authorization Length: 3 months] a exception is approved when there is documentation of

1. **INITIAL CRITERIA**: Inadequate response or inability to tolerate ALL of the following [Authorization length: 3 months]
   a. At least two triptans; and
   b. Non-steroidal antiinflamatory drugs (eg ibuprofen, naproxen); and
   c. Neuroleptics (eg prochlorperazine, metoclopramide); and
   d. Dihydroergotamine

2. REAUTHORIZATION CRITERIA: [Authorization length: 1 year]

Prescribed by or in consultation with a neurologist or a headache specialist

D. Buprenorphine/ naloxone (Bunavail®/Suboxone®/Zubsolv®) and buprenorphine (Subutex®) [Authorization length: 6 months] an exception for the treatment of opioid use disorder is approved when BOTH of the following inclusion criteria are met:

1. Used concurrently with comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self-help programs, behavioral therapy, or other psychosocial services); and
2. Documentation that a urine toxicology screen has been conducted

II. Quantity limit Criteria –

A. Opioid pain products [authorization = 1 year] An increased quantity of an opioid medication is approved when there is documentation of ALL of the following:

1. Current patient-prescriber opioid treatment agreement (signed within one year of request); and

2. The requested dose does not exceed FDA approved or accepted clinical dosing; and

3. ONE of the following:

    a. The dose cannot be achieved with commercially available clinical dosage forms; or

    b. Documentation indicating medical necessity for increased quantity (e.g. GI malabsorption)

B. Cough and cold products [Authorization Length: 1 month for initial; 6 months for reauthorizations] - An increased quantity of an opioid containing cough and cold medication is approved when there is documentation of ALL of the following:

a. The requested dose does not exceed FDA approved or accepted clinical dosing; and
b. Documentation of diagnosis requiring long-term therapy with requested cough/ cold medications; and
c. Inadequate response or inability to tolerate non-opioid therapies for the indication

C. Butalbital containing headache products [Authorization Length:1 year] - An increased quantity of a butalbital containing headache medication is approved when there is documentation of ALL of the following:

a. The requested dose does not exceed FDA approved or accepted clinical dosing; and
b. Inadequate response or inability to tolerate prophylactic therapy; and
c. Prescribed by or in consultation with a neurologist or headache specialist

D. Buprenorphine/ naloxone (Bunavail®/Suboxone®/Zubsolv®) and buprenorphine (Subutex®) [Authorization length: 6 months]**:** buprenorphine/ naloxone or buprenorphine for the treatment of opioid use disorder are approved in quantities greater than those specified in the policy when ALL of the following are met:

a. The requested dose does not exceed FDA approved or accepted clinical dosing; and

b. The dose cannot be achieved with commercially available dosage forms; and
c. Inadequate response to lower doses

Black Box Warning:

1. Respiratory depression: [21, 22, 30, 31, 32, 33, 34, 35, 40, 43] **TIRFs (Abstral®, Actiq®, Fentora®, Onsolis™, Subsys®), Lazanda®, Duragesic®, Hydromorphone (Dilaudid, Exalgo®), Methadone, Morphine Sulfate: Arymo™ ER, Avinza®, Kadian®, and MS Contin®, Morphabond ER®, Nucynta ER®/ Opana ER®, Oxycodone (Oxycontin®, oxycodone concentrate, Oxaydo™), Zohydro ER™** (hydrocodone ER), **Buprenorphine (Belbuca and Butrans)**

Fatal respiratory depression has occurred in patients treated with the above listed opioid products, including following use in opioid-intolerant patients and improper dosing. Be sure to monitor for sign and symptoms of respiratory depression, especially during initiation of the drugs. The substitution of fentanyl sublingual/buccal for any other fentanyl product may result in fatal overdose. Because of the risk of respiratory depression, fentanyl products are contraindicated for use as an as-needed analgesic, or in the management of acute or postoperative pain, including headache/migraine and in opioid-intolerant patients. In addition, the concomitant use of fentanyl sublingual with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations and may cause potentially fatal respiratory depression.

For hydromorphone and ER products like morphine ER, oxycodone ER, hydrocodone ER, tapentadol ER, and oxymorphone ER products, instruct patients to swallow a whole tablet. Crushing, chewing, snorting, or dissolving tablets can cause rapid release and absorption that could lead to fatal overdose and even death. Note: Avinza® capsule contents may be sprinkled on applesauce and swallowed without chewing[19]. Hydromorphone is a potent Schedule II controlled opioid agonist. Schedule II opioid agonists have the highest potential for abuse and risk of producing respiratory depression. Alcohol, other opioids, and CNS depressants (sedative-hypnotics) potentiate the respiratory depressant effects of hydromorphone, increasing the risk of respiratory depression that might result in death.

2. Medication errors: [32, 33] **TIRFs (Abstral®, Actiq®, Fentora®, Onsolis™, Subsys®), Lazanda®**

Substantial differences exist in the pharmacokinetic profile of fentanyl sublingual/buccal compared with other fentanyl products that result in clinically important 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 fentanyl products to fentanyl sublingual/buccal. When dispensing, do not substitute a fentanyl sublingual/buccal prescription for other fentanyl products.

3. Addiction and Abuse potential: [21, 22, 30, 31, 32, 33, 34, 42, 43] **TIRFs (Abstral®, Actiq®, Fentora®, Onsolis™, Subsys®), Lazanda®, Duragesic®, Hydromorphone (Dilaudid, Exalgo®), Methadone, Morphine Sulfate: Arymo™ ER, Avinza®, Kadian®, and MS Contin®, Morphabond ER®, Nucynta ER®/ Opana ER®, Oxycodone (Oxycontin®, oxycodone concentrate, Oxaydo™), Zohydro ER™** (hydrocodone ER), **Buprenorphine (Belbuca and Butrans)**

All opioid analgesics regardless of formulation are classified as Schedule II controlled substance, with high abuse liability. They expose patients and drug users to the risk of opioid addiction, abuse, and misuse, which can lead to overdose and death. Diversion, addiction, and abuse potential should be considered when prescribing or dispensing opioid analgesics. Providers must monitor all patients

regularly for the development of these behaviors or conditions. Due to the risk for misuse, abuse, addiction, and overdose, some products such as fentanyl sublingual/buccal is available only through a restricted program required by the Food and Drug Administration, called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, outpatients, health care providers who prescribe to outpatients, pharmacies, and distributors must enroll in the program. Further information is available at http://www.TIRFREMSaccess.com or by calling 1-866-822-1483.

4. Cytochrome P450 3A4 interaction: [30, 31] **TIRFs (Abstral®, Actiq®, Fentora®, Onsolis™, Subsys®), Lazanda®, Duragesic®, Oxycodone (Oxycontin®, oxycodone concentrate, Oxaydo™), Zohydro ER™** (hydrocodone ER)

The concomitant use of fentanyl, oxycodone ER and hydrocodone ER with all cytochrome P450 3A4 (CYP3A4) inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodone plasma concentration. Monitor patients receiving oxycodone ER and any CYP3A4 inhibitor or inducer.

5. Accidental exposure [21, 22, 30, 31, 32, 33, 34, 42, 43]**: Duragesic®, Hydromorphone (Dilaudid, Exalgo®), Methadone, Morphine Sulfate: Arymo™ ER, Avinza®, Kadian®, and MS Contin®, Morphabond ER® , Nucynta ER®/ Opana ER®, Oxycodone (Oxycontin®, oxycodone concentrate, Oxaydo™), Zohydro ER™, Buprenorphine (Belbuca and Butrans)**

Deaths due to a fatal overdose of the above listed opioid analgesics have occurred when children and adults were accidentally exposed to the drugs. Strict adherence to the recommended handling and disposal instructions is of the utmost importance to prevent accidental exposure. Accidental ingestion of even 1 dose, especially in children, can result in a fatal overdose and death.

6. Neonatal opioid withdrawal syndrome: [21, 22, 30, 31, 32, 33, 34, 44, 43]
Prolonged use of opioid analgesics especially **Duragesic®, Hydromorphone (Dilaudid, Exalgo®), Methadone, Morphine Sulfate: Arymo™ ER, Avinza®, Kadian®, and MS Contin®, Morphabond ER® , Nucynta ER®/ Opana ER® (**tapentadol ER, and oxymorphone ER), **Zohydro ER™, Oxycodone (Oxycontin®, oxycodone concentrate, Oxaydo™), Buprenorphine (Belbuca and Butran)** can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

7. Exposure to heat: Duragesic® [(31)]

Exposure of the fentanyl application site and surrounding area to direct external heat sources, such as heating pads or electric blankets, heat or tanning lamps, sunbathing, hot baths, saunas, hot tubs, and heated water beds may increase fentanyl absorption and has resulted in fatal overdose of fentanyl and death. Patients wearing fentanyl systems who develop fever or increased core body temperature due to strenuous exertion are also at risk for increased fentanyl exposure and may require an adjustment in the dose of fentanyl to avoid overdose and death.

8. Life-threatening QT prolongation: Methadone [29]

QT interval prolongation and serious arrhythmia like torsades de pointes have occurred during treatment with methadone. Most cases involve patients being treated for pain with large, multiple daily doses of methadone, although cases have been reported in patients receiving doses commonly used for maintenance treatment of opioid addiction. Closely monitor patients for changes in cardiac rhythm during initiation and titration of methadone.

9. Treatment of opioid addiction: Methadone[29]

For detoxification and maintenance of opioid dependence, methadone should be administered in accordance with the treatment standards cited in 42 CFR Section 8, including limitations on unsupervised administration.

10. Interaction with alcohol [21, 22, 30, 31, 32, 33, 34, 35, 40]**: Morphine Sulfate: Avinza®, Kadian®, and MS Contin®, Nucynta ER®/ Opana ER®, Zohydro ER™, Oxycodone (Oxycontin®, oxycodone concentrate, Oxaydo™), Buprenorphine (Belbuca and Butran)**

When using with alcohol, all opioid analgesic products have the potential to cause excessive sedation and may increase blood concentration of certain opioids like tapentadol, oxymorphone, and morphine. This could lead to fatal overdose and death. Instruct patients to avoid alcoholic beverages or use prescription or nonprescription products that contain alcohol while taking opioid analgesics.

11. Information about oral morphine and oxycodone solution[23, 29] **: Morphine Sulfate: Avinza®, Kadian®, and MS Contin®, Oxycodone (Oxycontin®, oxycodone concentrate, Oxaydo™)**

Morphine oral solution is available in 10 mg per 5 mL, 20 mg per 5 mL, and 100 mg per 5 mL (20 mg/mL) concentrations. The 100 mg per 5 mL (20 mg/mL) concentration is indicated for use in opioid-tolerant patients only. Take care when prescribing and administering morphine oral solution to avoid dosing errors due to confusion between different concentrations and between milligrams and milliliters, which could result in accidental overdose and death. Take care to ensure the proper dose is communicated and dispensed. Keep morphine oral solution out of the reach of children. In case of accidental ingestion, seek emergency medical help immediately.

Oxycodone concentrated oral solution is available as a 20 mg/mL concentration and is indicated for use in opioid-tolerant patients only. Take care when prescribing and administering oxycodone concentrated oral solution to avoid dosing errors due to confusion between milligram and milliliter, and other oxycodone solutions with different concentrations, which could result in accidental overdose and death. Take care to ensure the proper dose is communicated and dispensed. Keep oxycodone out of the reach of children. In case of accidental ingestion, seek emergency medical help immediately.

12. Abuse Deterrent Technology: Oxaydo™ [37]

This formulation incorporates Acura's patented AVERSION® (abuse-deterrent) Technology which Acura states is a patented mixture of gelling ingredients and nasal irritants designed to address common forms of opioid abuse. OXAYDO can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing in situations where there is concern about an increased risk of misuse or abuse. OXAYDO may be abused by crushing, chewing, snorting or injecting the product and these practices pose a significant risk to the abuser that could result in overdose and death.

A Risk Evaluation and Mitigation Strategy (REMS) is included in the label of the several medications. A

REMS is a safety strategy to manage known or potential serious risks associated with a medication and to enable patients to have continued access to such medicines by managing their safe use. Refer to the individual product labels for details on the REMS programs.

13. Risks from Concomitant Use with Benzodiazepines or other CNS Depressants: **Arymo™ ER [42], Morphabond ER®[43]**

Concomitant use of opioid with benzodiazepines or other CNS depressants may result in profound sedation, respiratory depressions, coma, and death.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

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Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

I. Transmucosal Immediate Release Fentanyl (TIRF) products

Brand name	Generic name
Abstral®	Fentanyl sublingual tablet
Actiq®	Fentanyl buccal lollipop
Fentora®	Fentanyl buccal tablet
Lazanda®	Fentanyl nasal solution
Onsolis®	Fentanyl buccal soluble film
Subsys®	Fentanyl sublingual liquid

II. High Dose opioids and long term use

Brand name	Generic name
Arymo® ER*	Morphine sulfate extended release tablet
Avinza®	Morphine sulfate extended release capsule 24HR
Belbuca®	Buprenorphine HCl
Butrans®	Buprenorphine patch
Dilaudid®	Hydromorphone immediate release
Duragesic® patch	Fentanyl transdermal patch 72 HR
Embeda® *	Morphine sulfate/naltrexone
Exalgo®	Hydromorphone tablet extended release 24HR Abuse deterrent
Hysingla® ER*	Hydrocodone ER
Various (e.g. Methadose)	Methadone
Kadian®	Morphine sulfate extended release 24HR capsule
Morphine sulfate tablet	Morphine sulfate tablet
NA	Morphine concentrate
MS Contin®, Morphabond®*	Morphine sulfate extended release tablet
Nucynta®	Tapendatol immediate release
Nucynta® ER	Tapendatol extended release
Opana®	Oxymorphone
Opana® ER	Oxymorphone
Oxy IR	Oxycodone immediate release
Oxycontin®	Oxycodone extended release
Xtampza® ER*	Oxycodone extended release
NA	Oxycodone highly concentrated
Zohydro®*	Hydrocodone ER

III. Appropriate Utilization with Medication Assistant Treatments (MAT) for opioid use disorder

Brand name	Generic name
Abstral®/Actiq®/Fentora®/Lazanda®/Subsys®/Onsolis®	Fentanyl immediate release
Avinza®	Morphine sulfate ER capsules
Butrans® patch	Buprenorphine patch
Capital/Codeine	APAP/Codeine liquid
Codeine sulfate	Codeine sulfate
Conzip®	Tramadol ER capsule
Demero®l/Meperitab®	Meperidine HCL
Dilaudid®	Hydromorphone tablets
Duragesic® patch	Fentanyl transdermal patch
Embeda®*	Morphine sulfate/naltrexone
Endocet®/Percocet®/Primlev®	Oxycodone/acetaminophen
Endodan®/Percodan®	Oxycodone/aspirin
Exalgo ®	Hydromorphone extended release tablet
Hycet®	Hydrocodone/acetaminophen liquid
Hydromorphone oral solution	Hydromorphone
Kadian®	Morphine sulfate ER capsules
Levorphanol tartrate tablets	Levorphanol tartrate
Meperidine oral solution	Meperidine liquid
Methadose®/Diskets®	Methadone
Morphine sulfate concentrate/oral solution/tablets	Morphine
MS Contin®, Morphabond®*	Morphine sulfate SR
Norco®/Lortab®/Vicodin®	Hydrocodone/acetaminophen tabs
Nucynta®	Tapentadol
Nycynta® ER	Tapentadol ER
Opana®	Oxymorphone HCL
Opana® ER	Oxymorphone HCL ER
Oxy IR/Roxicodone®	Oxycodone HCL
Oxycodone	Oxycodone solution; concentrate
Oxycontin® tablets	Oxycodone HCL ER
Roxicet®	Oxycodone/acetaminophen liquid
Tylenol® #3/Tylenol® #4	Acetaminophen/codeine
Ultracet®	Tramadol/acetaminophen
Ultram®	Tramadol
Ultram® ER	Tramadol ER
Vicoprofen®	Hydrocodone/ibuprofen
Xartemis® XR *	Oxycodone/acetaminophen ER
Xtampza® ER*	Oxycodone extended release

Zohydro® ER*/Hysingla® *	Hydrocodone bitartrate ER

DAYS' SUPPLY AND QUANTITY LIMITS Tables

Drug Name	**Maximum Quantity per Day**	**Five Days' Supply Limit**	**Quantity limit per rolling 30 days, unless otherwise specified (tablet, capsule)**	
Acetaminophen/codeine #2 300/15mg tab	12	Yes	360	
Acetaminophen/codeine #3 300/30mg tab (Tylenol®/codeine #3)	12	Yes	360	
Acetaminophen/codeine #4 300/60mg tab (Tylenol®/codeine #4)	6	Yes	180	
Acetaminophen/codeine liquid	90mL	Yes	2700mL	
Aspirin/codeine	6	Yes	180	
Buprenorphine film (Belbuca®) 75mcg, 150mcg	2	Yes	60	
Buprenorphine film (Belbuca®) 300 mcg and greater	2	No	60	
Buprenorphine patch (Butrans®)	NA	No	4 patches per 28 days	
Buprenorphine (Subutex®)	No	4	120	180 cumulative days' supply per 365 days
Buprenorphine/naloxone (Suboxone® 2/0.5mg, 4/1mg)	No	4	120	
Buprenorphine/ naloxone (Suboxone® 8/2mg)	No	3	90	
Buprenorphine/ naloxone (Suboxone® 12/3mg)	No	2	60	
Buprenorphine/naloxone (Zubsolv® 1.4/0.36mg, 2.9-0.71mg)	No	4	120	
Buprenorphine/naloxone (Zubsolv® 5.7/1.4mg)	No	3	90	
Buprenorphine/naloxone (Zubsolv® 8.6/2.1mg)	No	2	60	
Buprenorphine/naloxone (Zubsolv® 11.4-2.9mg)	No	1	30	
Buprenorphine/naloxone (Bunavail® 2.1/0.3mg)	No	4	120	
Buprenorphine/naloxone (Bunavail® 4.2/0.7mg)	No	3	90	
Buprenorphine/naloxone (Bunavail® 6.3/1mg)	No	1	30	
Butalbital/apap (Allzital®, Marten®)	6	Yes	180	
Butalbital/apap/caffeine with or without codeine (Esgic®, Fioricet®/codeine)	6	Yes	180	

Butalbital/asa/caffeine with or without codeine (Fiorinal®/Codeine)	6	Yes	180
Carisoprodol/ aspirin/ codeine (Soma® compound with codeine)	8	Yes	240
Codeine sulfate tablets 15mg, 30mg	12	Yes	360
Codeine sulfate tablets 60mg	6	Yes	180
Codeine sulfate solution	60mL	Yes	1800mL
Codeine/ chlorpheniramine susp (Tuzistra® XR)	20mL	Yes	600mL
Codeine/ chlorpheniramine solution (Z-Tuss® AC, Codar® AR)	60	Yes	1800mL
Codeine/ chlorpheniramine (Lexuss® 210)	80mL	Yes	2400mL
Codeine/ pyrilamine (Pro-clear® AC)	60mL	Yes	1800mL
Dihydrocodeine/ acetaminophen/ caffeine (Trezix®)	10	Yes	300
Dihydrocodeine/ aspirin/ caffeine (Synalgos®) 356.4-30-16 caps	10	Yes	300
Fentanyl IR (Abstral®, Actiq®, Fentora®, Onsolis®, Subsys®)	4	No	120
Fentanyl nasal solution (Lazanda®)	1	No	30 bottles
Fentanyl patch (Duragesic®)	NA	No	15 patches
Guaifenesin/ codeine (GG/codeine, Codar® GF, Coditussin® AC)	60mL	Yes	1800mL
Guaifenesin/ codeine (MAR-COF® CG)	45mL	Yes	900mL
Guaifenesin/ codeine (M-Clear® WC)	90mL	Yes	270mL
Hydrocodone bitartrate ER (Hysingla® ER*) 20mg, 30mg, 40mg, 60mg, 80mg	1	Yes	30
Hydrocodone bitartrate ER (Hysingla® ER*) 100mg and greater	1	No	30
Hydrocodone bitartrate ER (Zohydro® ER*) 10mg, 20mg, 30mg, 40mg	2	Yes	60
Hydrocodone bitartrate ER (Zohydro® ER*) 50mg and greater	2	No	60
Hydrocodone/acetaminophen 2.5/325mg, 5/300mg,7.5/300mg, 5/325mg, 7.5/325mg tab (Vicodin®, Norco®, Lortab®, Xodol®)	12	Yes	360
Hydrocodone/apap 10/325mg, 10/300mg tab (Vicodin®, Norco®, Lortab®, Xodol®)	6	Yes	180
Hydrocodone/apap liquid (10mg/325mg/15ml, 2.5mg/167mg/5ml, 5mg/333mg/10ml, 7.5mg/325mg/15ml, 10mg/300mg/15ml) (Hycet®)	90mL	Yes	2700mL
Hydrocodone/chlorpheniramine (Tussionex®)	10mL	Yes	300mL
Hydrocodone/chlorpheniramine (Vituz®)	20mL	Yes	600mL
Hydrocodone/chlorpheniramine (TussiCaps®)	2	Yes	60
Hydrocodone/chlorpheniramine/pseudoephedrine (Zutripro®)	20mL	Yes	600mL
Hydrocodone/ guaifenesin (Obredon®)	60mL	Yes	1800mL
Hydrocodone/ homatropine (Hydromet®)	30mL	Yes	900mL

Hydrocodone/ibuprofen (Vicoprofen®, Ibudone®, Reprexain®)	5	Yes	150
Hydrocodone/ pseudoephedrine (Rezira®)	20mL	Yes	600
Hydrocodone/pseudoephed/guaif (Hycofenix®)	40mL	Yes	1200mL
Hydromorphone (Dilaudid®) 2mg	6	Yes	180
Hydromorphone (Dilaudid®) 4mg and greater	6	No	180
Hydromorphone 1mg/1ml liquid (Dilaudid®)	12mL	Yes	360mL
Hydromorphone extended release (Exalgo®)	4	No	120
Levorphanol tartrate	6	Yes	180
Meperidine 50mg/5ml liquid	67mL	Yes	2000mL
Meperidine HCL (Demerol®, Meperitab®)	6	Yes	180
Meperidine/promethazine capsules (Meprozine®)	6	Yes	180
Morphine 10mg/5ml liquid	45 mL	Yes	1350 mL
Morphine 20mg/5ml liquid	23 mL	Yes	690 mL
Morphine concentrate 20mg/1ml, 10mg/0.5ml, 5mg/0.25ml liquid	6mL	No	180mL
Morphine sulfate IR (MSIR®)	6	Yes	180
Morphine sulfate ER capsules (Avinza®) 30mg, 45mg, 60mg, 75mg	1	Yes	30
Morphine sulfate ER capsules (Avinza®) 90mg and greater	1	No	30
Morphine sulfate ER capsules (Kadian®) 10mg, 20mg, 30mg, 40mg	2	Yes	60
Morphine sulfate ER capsules (Kadian®) 50mg and greater	2	No	60
Morphine sulfate SR (Morphabond®*) 15mg, 30mg	2	Yes	60
Morphine sulfate SR (Morphabond®*) 60mg, 100mg	2	No	60
Morphine sulfate SR (MS Contin®/Oramorph® SR, Arymo® ER*) 15mg, 30mg	3	Yes	90
Morphine sulfate SR (MS Contin®/Oramorph® SR, Arymo® ER*) 60mg and greater	3	No	90
Morphine sulfate/naltrexone (Embeda®*) 20/0.8mg, 30/1.2mg	2	Yes	60
Morphine sulfate/naltrexone (Embeda®*) 50/2mg and greater	2	No	60
Morphine suppositories 5mg	18	Yes	540
Morphine suppositories 10mg	6	Yes	180
Morphine suppositories 20mg	4	Yes	120
Oxycodone 5mg abuse deter tab (Oxaydo®*)	12	Yes	360
Oxycodone 7.5mg abuse deter tab (Oxaydo®*)	8	Yes	240
Oxycodone HCL (Oxy® IR/Roxicodone®) 5mg caps/tabs	12	Yes	360
Oxycodone HCL (Oxy® IR/Roxicodone®), 10mg caps/tabs	6	Yes	180
Oxycodone HCL (Oxy® IR/Roxicodone®)15mg and greater	6	No	180
Oxycodone 5mg/5ml liquid	60 mL	Yes	1800 mL

Oxycodone highly concentrated liquid 20mg/1ml liquid (Eth-Oxydose®)	6mL	No	180mL
Oxycodone HCL ER (Oxycontin®) 10mg, 15mg, 20mg	3	Yes	90
Oxycodone HCL ER (Oxycontin®) 30mg and greater	3	No	90
Oxycodone ER (Xtampza® ER*) 9mg, 13.5mg, 18mg	2	Yes	60
Oxycodone ER (Xtampza® ER*) 27mg and greater	2	No	60
Oxycodone/Acetaminophen, Endocet® (Percocet®,Primlev®) 2.5/325mg tab, 5/300mg, 5/325mg tab	12	Yes	360
Oxycodone/acetaminophen 7.5/325mg tab (Endocet®/Percocet®)	8	Yes	240
Oxycodone/acetaminophen 10/325mg tab (Endocet®/Percocet®)	6	Yes	180
Oxycodone/acetaminophen ER (Xartemis® XR*)	4	Yes	120
Oxycodone/acetaminophen 5mg/325mg/5ml liquid	60	Yes	1800 mL
Oxycodone/aspirin 4.8355/325mg tab	12	Yes	360
Oxycodone/ibuprofen tablets 5/400mg tab	4	Yes	120
Oxymorphone HCL (Opana®) 5mg	6	Yes	180
Oxymorphone HCL (Opana®)10mg	6	No	180
Oxymorphone HCL ER (Opana® ER) 5mg, 7.5mg, 10mg	3	Yes	90
Oxymorphone HCL ER (Opana® ER) 15mg and greater	3	No	90
Pentazocine/naloxone (Talwin® NX)	12	Yes	360
Phenylephrine/ brompheniramine/ codeine (M-End® PE)	90mL	Yes	2700mL
Phenylephrine/ chlorpheniramine/ codeine (Capcof®)	60mL	Yes	1800mL
Phenylephrine/ dexchlorpheniramine/ codeine (Pro-red® AC)	60mL	Yes	1800mL
Promethazine/codeine 6.25-10mg/5mL syrup	30mL	Yes	900mL
Promethazine/ phenylephrine/ codeine 6.25-5-10mg/5mL	30mL	Yes	900mL
Pseudoephedrine/ brompheniramine/ codeine (MAR-COF® BP, CPB® WC)	60mL	Yes	1800mL
Pseudoephedrine/ brompheniramine/ codeine (M-End® WC)	90mL	Yes	2700mL
Pseudoephedrine/ chlorpheniramine/ codeine (Tricode® AR)	40mL	Yes	2400mL
Pseudoephedrine/ codeine (Codar® D)	40mL	Yes	2400mL
Pseudoephedrine/ dexbrompheniramine/ codeine (M-End® Max D)	60mL	Yes	1800mL
Tapentadol (Nucynta®) 50mg	4	Yes	120
Tapentadol (Nucynta®) 75mg, 100mg	6	No	180

Tapentadol ER (Nucynta® ER) 50mg, 100mg	2	Yes	60
Tapentadol ER (Nucynta® ER) 150mg and greater	2	No	60
Tramadol (Ultram®)	8	No	240
Tramadol (Ultram® ER and Conzip®)	1	No	30
Tramadol/acetaminophen (Ultracet®)	40/5 days	No	40/5 days

*** Opioids with abuse deterrent properties**

Cross References:

N/A

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