Opioids Extended Release (ER) Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date 04-28-2025 | Date of Origin

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Belbuca® (buprenorphine) Buccal film	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. • Product is not indicated as an as-needed (prn) analgesic.		5
Butrans® (buprenorphine) Transdermal patch*	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. • Product is not indicated as an as-needed (prn) analgesic.	*generic available	6
ConZip ®, Tramadol Extended-Release Capsule Extended-Release Tablet*	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment	*generic available	7,19

Agent(s)	FDA Indication(s)	Notes	Ref#
	options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.		
fentanyl Transdermal patch*	Management of severe and persistent pain in opioid-tolerant patients that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.	*generic available	10
hydromorphone Extended-Release Tablet*	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.	*generic available	9
Hysingla ER® (hydrocodone) Extended-Release Tablet	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.		11
Morphine Sulfate	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate		12,14

Agent(s)	FDA Indication(s)	Notes	Ref#
Extended-Release Capsule	Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.		
MS Contin® (morphine sulfate) Extended-Release Tablet*	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.	*generic available	15
Nucynta ER ® (tapentadol) Extended-Release Tablet	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Management of severe and persistent neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve this product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.		16
Oxycontin®, Oxycodone Extended-Release Tablet	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate in: • Adults		17

Agent(s)	FDA Indication(s)	Notes	Ref#
	• Opioid-tolerant pediatric patients 11 years of age and older who are already receiving and tolerate a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve this product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.		
Oxymorphone Extended-Release Tablet	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. • Product is not indicated as an as-needed (prn) analgesic.		18
Xtampza ER® (oxycodone) Extended-Release Capsule	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.		20
Hydrocodone Extended-Release Capsule	Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate Limitations of Use: • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration and because of the greater risks of overdose and death with		21

Agent(s)	FDA Indication(s)	Notes	Ref#
	extended-release/long-acting opioid formulations, reserve product for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain . • Product is not indicated as an as-needed (prn) analgesic.		

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Chronic Pain	The Centers for Disease Control and Prevention (CDC) guidelines define acute pain as pain with abrupt onset and caused by an injury or other process that is not ongoing. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.(1) Use of tramadol or codeine containing products in pediatric patients has caused life-threatening respiratory depression, with some of the reported cases occurring post-tonsillectomy and/or adenoidectomy. Ultra-rapid metabolizers are at increased risk of life-threatening respiratory depression due to a CYP2D6 polymorphism. Use in children under 12 years of age is contraindicated for these products, and for those between the ages of 12 and 18 years when used for post-operative pain management following tonsillectomy and/or adenoidectomy.(3) The CDC defines chronic pain as pain that continues or is expected to continue more than three months or past the time of normal tissue healing. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. The Food and Drug Administration (FDA) modified labeling of ER/LA opioids, indicating they should be reserved for management of severe pain requiring daily, around-the-clock, long term opioid treatment. The CDC indicates ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week. Assessment should be done to determine if continued opioid therapy is needed.(1) The American Society of Interventional Pain Physicians (ASIPP) 2023 Comprehensive Evidence-Based Consensus Guidelines for Prescription of Opioids for Chronic Non-Cancer Pain states that there is similar effectiveness for long and short-acting opioids, with increased adverse consequences of long-acting opioids. High doses of long-acting agents should only be used in limited circumstances wherein the management of severe, intractable pain is not responsive or mitigated by short-acting opioids or moderate doses of long-acting opioids. The guidelines recommend the following for the treatment of chronic non-cancer pain:(2) • Initial steps with opioid therapy: o Complete a comprehensive evaluation of pain and medical history including previous treatments, psychosocial history, functional assessment and appropriate consultations are recommended prior to initiation of opioid therapy o Perform risk stratification, review prescription drug monitoring programs (PDMPs) data prior to initiating any/all controlled substances

	and periodically or as mandated by regulations during treatment, conduct urine drug testing (UDT) initially and periodically for compliance monitoring o Discuss the realistic benefits and known risks with patients. Establish clear treatment goals for pain and/or function, and as possible, improvement in quality of life. Discuss and plan how opioid therapy will be discontinued if benefits do not outweigh risks and/or meaningful, realistic improvement is not achieved from opioid therapy o Complete a controlled substance agreement that is detailed with each item, include safe storage and disposal, and initialed and signed by the patient o Once medical necessity is established, opioid therapy may be initiated using low doses and short-acting drugs, with appropriate monitoring to provide effective relief and avoid side effects. Long-acting opioids should not be utilized for the initiation of opioid therapy • Assessment of effectiveness of opioid therapy: o Assess meaningful benefit (i.e., at least 30% benefit in pain and/or function) improvement based on analgesia, activity, and ensure opioid therapy does not incur aberrant behaviors and adverse effects o Clinicians must understand the effectiveness, viability, limitations, adverse consequences, and relative value (versus burden/risk) of long-term opioid therapy in chronic non-cancer pain o Evidence of effectiveness is similar for long-acting and short-acting opioids with increased prevalence of adverse consequences of long-acting opioids o Long-acting opioids in high doses are recommended only in specific circumstances with severe intractable pain that is not amenable to short-acting opioids or moderate doses of long-acting opioids o Tapering or weaning process must be initiated slowly after appropriate criteria have been met and should entail slow tapering of the dosage across a specified period of time. Reinstitution of opioid therapy can be considered when such treatment is deemed medically necessary if the patient's behavior and patter of drug use are shown to be stable, and if results of at least 2 consistent urine drug tests are negative for opioids and/or illicit drugs • Monitoring adherence and side effects: o Adherence monitoring to assess and sustain appropriate use must be instituted at proper intervals, as based on risk stratification and indication(s) of other issues that may be regarded as negatively influencing therapeutic compliance o Monitor and manage side effects appropriately, including bowel function o Chronic opioid therapy may be continued, with continuous adherence monitoring, and modified in conjunction with or after failure of other modalities of treatments The 2022 CDC guidelines for Prescribing Opioids for Pain recommend the following for prescribing opioids for acute, subacute, and chronic pain:(1) • When to initiate or continue opioids for chronic pain: o Clinicians should maximize use of non-pharmacologic and non-opioid pharmacologic therapies prior to initiating opioid therapy as appropriate for the specific condition and patient o Clinicians should consider opioids only if expected benefits for both pain and function are anticipated to outweigh risks to the patients o Clinicians should establish treatment goals with all patients prior to starting opioid therapy for chronic pain. Goals should include realistic goals for pain and function, and how to discontinue therapy if benefits do not outweigh the risks. Clinicians should only continue therapy with opioids if there is clinically meaningful improvement in pain and function that outweigh the risks to patient safety

	○ Clinicians should discuss the risks and realistic benefits of opioid therapy prior to starting therapy and periodically during therapy • Opioid selection, dosage, duration, follow-up, and discontinuation: ○ Clinicians should prescribe immediate release opioids instead of extended release/long-acting opioids when starting opioid therapy for acute, subacute, or chronic pain ○ The lowest effective dose should be prescribed when opioids are started. Clinicians should use caution when prescribing opioids, should reassess evidence of benefits and risks when increasing doses to greater than or equal to 50 MME/day, as many patients do not experience benefit in pain or function when doses are increased beyond 50 MME/day. Exposure to doses over 50 MME/day put patients at increased risk of harm, including opioid misuse ○ Opioids for acute pain should be prescribed at the lowest effective dose of immediate release opioids and should be prescribed at a quantity no greater than necessary for the expected duration of pain. Benefits and risks should be evaluated at least every 2 weeks after initiating opioid therapy, and if opioid use is required beyond 1 month, clinicians should ensure reversible causes of pain are addressed and that opioid prescribing for acute pain does not become long-term opioid therapy simply due to lack of appropriate reassessment ○ Benefits and risks should be evaluated within 1 to 4 weeks after starting opioid therapy for subacute or chronic pain or of dose escalations. Benefits and risks of continued therapy should be evaluated every 3 months or more frequently ○ Clinicians should re-evaluate patients at higher risk for opioid use disorder (e.g., patients with mental health conditions or depression, patients with a history of substance abuse, history of overdose, taking more than 50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months • Assessing risk and addressing harms of opioid use: ○ Clinicians should incorporate into the management plan strategies to mitigate risk, including offering naloxone when there is increased risk of opioid overdose, such as history of overdose, history of substance abuse disorder, higher opioid dosages (greater than or equal to 50 MME/day), or concurrent benzodiazepine use ○ When initiating opioid therapy for acute, subacute, or chronic pain, and periodically during opioid therapy for subacute or chronic pain, clinicians should review a patient's history of controlled substance prescriptions using the states prescription drug monitoring program (PDMP) data to determine if the patient is receiving opioid dosages or combinations that put the patient at high risk for overdose. ○ Clinicians should consider the benefits and risks of toxicology testing when prescribing opioids for subacute or chronic pain ○ Clinicians should use particular caution when prescribing opioid pain medication and benzodiazepines concurrently and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants The CDC guideline for opioid prescribing note that patients with cancer, sickle cell disease, and patients receiving palliative or end of life care are exempt from these recommendations. The guideline also states that although identification of an opioid use disorder can alter the expected benefits and risks of opioid therapy for pain, patients with co-occurring pain and substance use disorder require ongoing pain management that maximizes benefits relative to risks. Clinicians should continue to use non-pharmacologic and non-opioid pharmacologic pain treatments as appropriate and consider consulting a pain specialist as needed to provide optimal pain management.(1)

Safety	The concurrent use of opioid agonists with buprenorphine or buprenorphine/naloxone should be avoided. Such concurrent use may reduce analgesic effect and/or may precipitate withdrawal symptoms.(5-7, 9-12, 14-21) All agents contain the following boxed warnings:(5-7, 9-12, 14-21) • Addiction, Abuse, and Misuse: Product exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing product and reassess all patients regularly for the development of these behaviors and conditions • Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS): To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a REMS for these products. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to healthcare providers. Healthcare providers are strongly encouraged to: o Complete a REMS-compliant education program, o Counsel patients and/or their caregivers, with every prescription, on safe use, serious risks, storage, and disposal of these products, o Emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacist, and o Consider other tools to improve patient, household, and community safety. • Life-Threatening Respiratory Depression: Serious, life-threatening, or fatal respiratory depression may occur with use of product, even when used as recommended. To reduce the risk of respiratory depression, proper dosing and titration of the product are essential. Monitor for respiratory depression, especially during initiation of product or following a dose increase o Oral products: Instruct patients to swallow product whole (for some capsules, contents may be sprinkled on applesauce and swallowed immediately without chewing); breaking, crushing, chewing, or dissolving product can cause rapid release and absorption of a potentially fatal dose of product o Belbuca, Butrans: Misuse or abuse of these products by chewing, swallowing, snorting, or injecting buprenorphine extracted from the film/patch will result in uncontrolled delivery of buprenorphine and pose a significant risk of overdose and death o Fentanyl transdermal patches: Due to risk of respiratory depression, patches are contraindicated for use as an as-needed analgesic, in non-opioid tolerant patients, in acute pain, and in postoperative pain • Accidental Ingestion/Exposure: Accidental ingestion/exposure of even one dose of product, especially by children, can result in a fatal overdose of product o Fentanyl products also note deaths due to an overdose have occurred when children and adults were accidentally exposed. Strict adherence to the recommended handling and disposal instructions is of the utmost importance to prevent accidental exposure • Neonatal Opioid Withdrawal Syndrome: Prolonged use of product during pregnancy 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 • Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants: Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death:

	o Reserve concomitant prescribing of product and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate. o Limit dosages and durations to the minimum required. o Follow patients for signs and symptoms of respiratory depression and sedation. Tramadol products contain the following additional boxed warnings:(7,19) • Ultra-Rapid Metabolism of tramadol and Other Risk Factors For Life-Threatening Respiratory Depression In Children: Life-threatening respiratory depression and death have occurred in children who received tramadol. Some of the reported cases occurred following tonsillectomy and/or adenoidectomy, and at least one case, the child had evidence of being an ultra-rapid metabolizer of tramadol due to a CYP2D6 polymorphism. Tramadol is contraindicated in children younger than 12 years of age and in children younger than 18 years of age following tonsillectomy and/or adenoidectomy. Avoid the use of tramadol in adolescents 12 to 18 years of age who have other risk factors that may increase their sensitivity to the respiratory depressant effects of tramadol. • Interactions with Drugs Affecting Cytochrome P450 Isoenzymes: The effects of concomitant use or discontinuation of cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with tramadol are complex. Use of cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with tramadol requires careful consideration of the effects on the parent drug, tramadol, and the active metabolite. Fentanyl products contain the following additional boxed warnings:(10) • Cytochrome P450 3A4 Interaction: The concomitant use of fentanyl with all cytochrome P450 3A4 inhibitors may result in an increase in fentanyl 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 fentanyl plasma concentration. Monitor patients receiving fentanyl and any CYP3A4 inhibitor or inducer. • Risk of Increased Fentanyl Absorption with Application of External Heat: 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. Warn patients to avoid exposing the application site and surrounding area to direct external heat sources. Oxycodone and hydrocodone products contain the following additional boxed warning:(11,17,20,21) • Cytochrome P450 3A4 Interaction: The concomitant use of oxycodone/hydrocodone with all cytochrome P450 3A4 inhibitors may result in an increase in oxycodone/hydrocodone 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/hydrocodone plasma concentration. Monitor patients receiving oxycodone/hydrocodone and any CYP3A4 inhibitor or inducer. Oxymorphone, Morphine sulfate ER capsules, Nucynta and Hydrocodone ER contain the following additional boxed warning:(12,14,15,16,18, 21) • Interaction with Alcohol: Instruct patients not to consume alcoholic beverages or use prescription or non-prescription products that contain alcohol while taking product. The co-ingestion of alcohol with product may result in increased plasma levels and a potentially fatal overdose. Morphine ER products have the following contraindications for use:(12,14,15) • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Concurrent use of monoamine oxidase inhibitors (MAOIs) or use within the last 14 days • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to morphine • Significant respiratory depression Buprenorphine products have the following contraindications for use:(5,6) • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity (e.g., anaphylaxis) to buprenorphine • Significant respiratory depression Tramadol products have the following contraindications for use:(7,19) • Hypersensitivity to tramadol • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • All children younger than 12 years of age • Post-operative pain management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy • Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days • Known or suspected gastrointestinal obstruction, including paralytic ileus • Significant respiratory depression Fentanyl products have the following contraindications for use:(10) • Opioid non-tolerant patients • Acute or intermittent pain, postoperative pain, mild pain • Known or suspected GI obstruction, including paralytic ileus

	• Known hypersensitivity to fentanyl or any of the components of the transdermal system • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Significant respiratory depression Hydromorphone ER has the following contraindications for use:(9) • Opioid non-tolerant patients • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Surgical procedures and/or underlying disease resulting in narrowing of the gastrointestinal tract, or have "blind loops" of the gastrointestinal tract or gastrointestinal obstruction • Hypersensitivity (e.g., anaphylaxis) to hydromorphone or sulfite-containing medications • Significant respiratory depression Hydrocodone ER products have the following contraindications for use:(11,21) • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity to any component or hydrocodone bitartrate • Significant respiratory depression Nucynta ER has the following contraindications for use:(16) • Acute or severe bronchial asthma • Known or suspected paralytic ileus • Hypersensitivity to tapentadol or to any other ingredients of the product • Concurrent use of monoamine oxidase inhibitors (MAOI) or use within the last 14 days • Significant respiratory depression Oxycodone ER products have the following contraindications for use:(17,20) • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected gastrointestinal obstruction, including paralytic ileus • Hypersensitivity (e.g., anaphylaxis) to oxycodone • Significant respiratory depression Oxymorphone ER products have the following contraindications for use:(18) • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment

	• Known or suspected gastrointestinal obstruction, including paralytic ileus • Moderate and severe hepatic impairment • Hypersensitivity (e.g., anaphylaxis) to oxymorphone • Significant respiratory depression

REFERENCES

Number	Reference
1	Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.
2	Manchikanti L, Kaye AM, Knezevic NN, et al. Comprehensive, Evidence-Based, Consensus Guidelines for Prescription of Opioids for Chronic Non-Cancer Pain from the American Society of Interventional Pain Physicians (ASIPP) guidelines. Pain Physician Journal. 2023;26:S7-S126.
3	FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. January 2018. Accessed August 2024.
4	Reference no longer used.
5	Belbuca prescribing information. BioDelivery Sciences International Inc. December 2023.
6	Butrans prescribing information. Purdue Pharma LP. June 2024.
7	Conzip prescribing information. Vertical Pharmaceuticals Inc. December 2023.
8	Reference No longer used.
9	Hydromorphone ER prescribing information. Ascent Pharmaceuticals, Inc. Padagis US LLC. January 2024.
10	Fentanyl patch prescribing information. SpecGx, LLC. December 2023.
11	Hysingla ER prescribing information. Purdue Pharma LP. December 2023.
12	Morphine sulfate ER capsule prescribing information. Upsher-Smith Laboratories, LLC. March 2024.
13	Reference no longer used.
14	Morphine sulfate ER prescribing information. Actavis Pharma, Inc. November 2023.
15	MS Contin prescribing information. Rhodes Pharmaceuticals L.P. December 2023.
16	Nucynta ER prescribing information. Janssen Pharmaceuticals Inc. December 2023.
17	OxyContin prescribing information. Purdue Pharma L.P. May 2024.
18	Oxymorphone prescribing information. Amneal Pharmaceuticals LLC. August 2022.
19	Tramadol ER prescribing information. Sun Pharmaceuticals Industries, Inc. December 2023.
20	Xtampza prescribing information. Collegium Pharmaceuticals, Inc. December 2023.
21	Hydrocodone ER prescribing information. Alvogen Inc. December 2023.

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	fentanyl td patch	100 MCG/HR ; 12 MCG/HR ; 25	15	Patches	30	DAYS	Program max daily dose 100mcg/hr patch/2 days		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
		MCG/HR ; 37.5 MCG/HR ; 50 MCG/HR ; 62.5 MCG/HR ; 75 MCG/HR ; 87.5 MCG/HR							
	hydromorphone hcl tab er	12 MG ; 16 MG ; 32 MG ; 8 MG	30	Tablets	30	DAYS	Program max daily dose 32mg		
Belbuca	buprenorphine hcl buccal film	150 MCG ; 300 MCG ; 450 MCG ; 600 MCG ; 75 MCG ; 750 MCG ; 900 MCG	60	Films	30	DAYS	Program max daily dose 1800mcg		
Butrans	buprenorphine td patch weekly	10 MCG/HR ; 15 MCG/HR ; 20 MCG/HR ; 5 MCG/HR ; 7.5 MCG/HR	4	Systems	28	DAYS	Program max daily dose 20mcg/hr system/week		
Conzip ; Tramadol hcl er	tramadol hcl cap er	100 MG ; 200 MG ; 300 MG	30	Capsules	30	DAYS	Program max daily dose 300mg		
Hydrocodone bitartrate er	hydrocodone bitartrate cap er	10 MG ; 15 MG ; 20 MG ; 30 MG ; 40 MG ; 50 MG	60	Capsules	30	DAYS	Program max daily dose 100mg		
Hydrocodone bitartrate er ; Hysingla er	hydrocodone bitartrate tab er	100 MG ; 120 MG ; 20 MG ; 30 MG ; 40 MG ; 60 MG ; 80 MG	30	Tablets	30	DAYS	Program max daily dose 120mg		
Morphine sulfate er	morphine sulfate beads cap er	120 MG ; 30 MG ; 45 MG ; 60 MG ; 75 MG ; 90 MG	30	Capsules	30	DAYS	Program max daily dose 240mg		
Morphine sulfate er	morphine sulfate cap er	10 MG ; 100 MG ; 20 MG ; 30 MG ; 50 MG ; 60 MG ; 80 MG	60	Capsules	30	DAYS	Program max daily dose 400mg		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Ms contin	morphine sulfate tab er	100 MG ; 15 MG ; 200 MG ; 30 MG ; 60 MG	90	Tablets	30	DAYS	Program max daily dose 600mg		
Nucynta er	tapentadol hcl tab er	100 MG ; 150 MG ; 200 MG ; 250 MG ; 50 MG	60	Tablets	30	DAYS	Program max daily dose 500mg		
Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 10 MG	10 MG	60	Tablets	30	DAYS	Program max daily dose 160mg		
Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 20 MG	20 MG	60	Tablets	30	DAYS	Program max daily dose 160mg		
Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 40 MG	40 MG	60	Tablets	30	DAYS	Program max daily dose 160mg		
Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 80 MG	80 MG	120	Tablets	30	DAYS	Program max daily dose 160mg		
Oxycontin	Oxycodone HCl Tab ER 12HR Deter 15 MG	15 MG	60	Tablets	30	DAYS	Program max daily dose 160mg		
Oxycontin	Oxycodone HCl Tab ER 12HR Deter 30 MG	30 MG	60	Tablets	30	DAYS	Program max daily dose 160mg		
Oxycontin	Oxycodone HCl Tab ER 12HR Deter 60 MG	60 MG	120	Tablets	30	DAYS	Program max daily dose 160mg		
Oxymorphone hydrochloride	oxymorphone hcl tab er	10 MG ; 15 MG ; 20 MG ; 30 MG ; 40 MG ; 5 MG ; 7.5 MG	60	Tablets	30	DAYS	Program max daily dose 80mg		
Tramadol hcl er	tramadol hcl tab er	100 MG ; 200 MG ; 300 MG	30	Tablets	30	DAYS	Program max daily dose 300mg		
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 13.5 MG	13.5 MG	60	Capsules	30	DAYS	Program max daily dose 288mg		
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 18 MG	18 MG	60	Capsules	30	DAYS	Program max daily dose 288mg		
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 27 MG	27 MG	60	Capsules	30	DAYS	Program max daily dose 288mg		
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 36 MG	36 MG	240	Capsules	30	DAYS	Program max daily dose 288mg		
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 9 MG	9 MG	60	Capsules	30	DAYS	Program max daily dose 288mg		

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
651000250086		fentanyl td patch	100 MCG/HR ; 12 MCG/HR ; 25 MCG/HR ; 37.5 MCG/HR ; 50 MCG/HR ; 62.5 MCG/HR ; 75 MCG/HR ; 87.5 MCG/HR	Program max daily dose 100mcg/hr patch/2 days			
651000351075		hydromorphone hcl tab er	12 MG ; 16 MG ; 32 MG ; 8 MG	Program max daily dose 32mg			
652000101082	Belbuca	buprenorphine hcl buccal film	150 MCG ; 300 MCG ; 450 MCG ; 600 MCG ; 75 MCG ; 750 MCG ; 900 MCG	Program max daily dose 1800mcg			
652000100088	Butrans	buprenorphine td patch weekly	10 MCG/HR ; 15 MCG/HR ; 20 MCG/HR ; 5 MCG/HR ; 7.5 MCG/HR	Program max daily dose 20mcg/hr system/week			
651000951070	Conzip ; Tramadol hcl er	tramadol hcl cap er	100 MG ; 200 MG ; 300 MG	Program max daily dose 300mg			
651000301069	Hydrocodone bitartrate er	hydrocodone bitartrate cap er	10 MG ; 15 MG ; 20 MG ; 30 MG ; 40 MG ; 50 MG	Program max daily dose 100mg			
6510003010A8	Hydrocodone bitartrate er ; Hysingla er	hydrocodone bitartrate tab er	100 MG ; 120 MG ; 20 MG ; 30 MG ; 40 MG ; 60 MG ; 80 MG	Program max daily dose 120mg			
651000552070	Morphine sulfate er	morphine sulfate beads cap er	120 MG ; 30 MG ; 45 MG ; 60 MG ; 75 MG ; 90 MG	Program max daily dose 240mg			
651000551070	Morphine sulfate er	morphine sulfate cap er	10 MG ; 100 MG	Program max daily dose 400mg			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
			; 20 MG ; 30 MG ; 50 MG ; 60 MG ; 80 MG				
651000551004	Ms contin	morphine sulfate tab er	100 MG ; 15 MG ; 200 MG ; 30 MG ; 60 MG	Program max daily dose 600mg			
651000911074	Nucynta er	tapentadol hcl tab er	100 MG ; 150 MG ; 200 MG ; 250 MG ; 50 MG	Program max daily dose 500mg			
6510007510A710	Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 10 MG	10 MG	Program max daily dose 160mg			
6510007510A720	Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 20 MG	20 MG	Program max daily dose 160mg			
6510007510A740	Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 40 MG	40 MG	Program max daily dose 160mg			
6510007510A780	Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 80 MG	80 MG	Program max daily dose 160mg			
6510007510A715	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 15 MG	15 MG	Program max daily dose 160mg			
6510007510A730	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 30 MG	30 MG	Program max daily dose 160mg			
6510007510A760	Oxycontin	Oxycodone HCl Tab ER 12HR Deter 60 MG	60 MG	Program max daily dose 160mg			
651000801074	Oxymorphone hydrochloride	oxymorphone hcl tab er	10 MG ; 15 MG ; 20 MG ; 30 MG ; 40 MG ; 5 MG ; 7.5 MG	Program max daily dose 80mg			
651000951075	Tramadol hcl er	tramadol hcl tab er	100 MG ; 200 MG ; 300 MG	Program max daily dose 300mg			
6510007500A315	Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 13.5 MG	13.5 MG	Program max daily dose 288mg			
6510007500A320	Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 18 MG	18 MG	Program max daily dose 288mg			
6510007500A330	Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 27 MG	27 MG	Program max daily dose 288mg			
6510007500A340	Xtampza er	Oxycodone Cap ER 12HR	36 MG	Program max daily dose 288mg			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		Abuse-Deterrent 36 MG					
6510007500A310	Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 9 MG	9 MG	Program max daily dose 288mg			

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	fentanyl td patch	100 MCG/HR ; 12 MCG/HR ; 25 MCG/HR ; 37.5 MCG/HR ; 50 MCG/HR ; 62.5 MCG/HR ; 75 MCG/HR ; 87.5 MCG/HR	Commercial ; HIM ; ResultsRx
	hydromorphone hcl tab er	12 MG ; 16 MG ; 32 MG ; 8 MG	Commercial ; HIM ; ResultsRx
Belbuca	buprenorphine hcl buccal film	150 MCG ; 300 MCG ; 450 MCG ; 600 MCG ; 75 MCG ; 750 MCG ; 900 MCG	Commercial ; HIM ; ResultsRx
Butrans	buprenorphine td patch weekly	10 MCG/HR ; 15 MCG/HR ; 20 MCG/HR ; 5 MCG/HR ; 7.5 MCG/HR	Commercial ; HIM ; ResultsRx
Conzip ; Tramadol hcl er	tramadol hcl cap er	100 MG ; 200 MG ; 300 MG	Commercial ; HIM ; ResultsRx
Hydrocodone bitartrate er	hydrocodone bitartrate cap er	10 MG ; 15 MG ; 20 MG ; 30 MG ; 40 MG ; 50 MG	Commercial ; HIM ; ResultsRx
Hydrocodone bitartrate er ; Hysingla er	hydrocodone bitartrate tab er	100 MG ; 120 MG ; 20 MG ; 30 MG ; 40 MG ; 60 MG ; 80 MG	Commercial ; HIM ; ResultsRx
Morphine sulfate er	morphine sulfate beads cap er	120 MG ; 30 MG ; 45 MG ; 60 MG ; 75 MG ; 90 MG	Commercial ; HIM ; ResultsRx
Morphine sulfate er	morphine sulfate cap er	10 MG ; 100 MG ; 20 MG ; 30 MG ; 50 MG ; 60 MG ; 80 MG	Commercial ; HIM ; ResultsRx
Ms contin	morphine sulfate tab er	100 MG ; 15 MG ; 200 MG ; 30 MG ; 60 MG	Commercial ; HIM ; ResultsRx
Nucynta er	tapentadol hcl tab er	100 MG ; 150 MG ; 200 MG ; 250 MG ; 50 MG	Commercial ; HIM ; ResultsRx
Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 10 MG	10 MG	Commercial ; HIM ; ResultsRx
Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 20 MG	20 MG	Commercial ; HIM ; ResultsRx
Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 40 MG	40 MG	Commercial ; HIM ; ResultsRx
Oxycodone hydrochloride e ; Oxycontin	Oxycodone HCl Tab ER 12HR Deter 80 MG	80 MG	Commercial ; HIM ; ResultsRx
Oxycontin	Oxycodone HCl Tab ER 12HR Deter 15 MG	15 MG	Commercial ; HIM ; ResultsRx
Oxycontin	Oxycodone HCl Tab ER 12HR Deter 30 MG	30 MG	Commercial ; HIM ; ResultsRx
Oxycontin	Oxycodone HCl Tab ER 12HR Deter 60 MG	60 MG	Commercial ; HIM ; ResultsRx
Oxymorphone hydrochloride	oxymorphone hcl tab er	10 MG ; 15 MG ; 20 MG ; 30 MG ; 40 MG ; 5 MG ; 7.5 MG	Commercial ; HIM ; ResultsRx
Tramadol hcl er	tramadol hcl tab er	100 MG ; 200 MG ; 300 MG	Commercial ; HIM ; ResultsRx
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 13.5 MG	13.5 MG	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 18 MG	18 MG	Commercial ; HIM ; ResultsRx
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 27 MG	27 MG	Commercial ; HIM ; ResultsRx
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 36 MG	36 MG	Commercial ; HIM ; ResultsRx
Xtampza er	Oxycodone Cap ER 12HR Abuse-Deterrent 9 MG	9 MG	Commercial ; HIM ; ResultsRx

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	Program Maximum Daily Doses

Agent(s)	Program Maximum Daily Dose
Belbuca (buprenorphine buccal film)	1800 mcg
Butrans (buprenorphine transdermal system)	20 mcg/hr system/week
ConZip, Tramadol (tramadol ER) capsules	300 mg
fentanyl transdermal patch	100 mcg/hr patch/2 days
Hysingla ER (hydrocodone ER) tablets	120 mg
Morphine Sulfate ER capsules	400 mg
Morphine Sulfate ER capsules (beads)	240 mg
MS Contin (morphine sulfate ER) tablets	600 mg
Nucynta ER (tapentadol ER) tablets	500 mg
OxyContin (oxycodone ER) tablets	160 mg
Oxymorphone ER tablets	80 mg
tramadol ER tablets	300 mg
Xtampza ER (oxycodone ER) capsules	288 mg
Hydrocodone ER capsules	100 mg
Hydromorphone ER tablets	32 mg

Quantity limit for the Target Agent(s) will be approved when ONE of the following is met:

1. BOTH of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit AND
   B. If the requested agent contains tramadol, dihydrocodeine, or codeine, then ONE of the following:
      1. The patient is 12 to less than 18 years of age AND the requested opioid will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy OR
      2. The patient is 18 years of age or over OR
2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
   A. The requested quantity (dose) is less than or equal to the Program Maximum Daily dose (maximum mg allowed with highest dosage strength) AND ALL of the following:

Module	Clinical Criteria for Approval
	1. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit AND 2. There is support for therapy with a higher dose for the intended diagnosis AND 3. If the requested agent contains tramadol, dihydrocodeine, or codeine, then ONE of the following: A. The patient is 12 to less than 18 years of age AND the requested opioid will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy OR B. The patient is 18 years of age or over OR B. The requested quantity (dose) is greater than the Program Maximum Daily Dose (maximum mg allowed with highest dosage strength) AND ALL of the following: 1. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit AND 2. ONE of the following: A. The patient has a diagnosis of active cancer pain due to an active malignancy OR B. The patient is eligible for hospice OR palliative care OR C. The patient has a diagnosis of sickle cell disease OR D. The patient is undergoing treatment of chronic non-cancer pain and ALL of the following: 1. A formal, consultative evaluation which includes ALL of the following has been conducted: A. Diagnosis AND B. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy AND C. The need for continued opioid therapy has been assessed AND 2. A patient-specific pain management plan is on file for the patient AND 3. The prescriber has reviewed the patient's records in the state's prescription drug monitoring program (PDMP) AND has determined that the opioid dosages and combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose AND 3. There is support for therapy with a higher dose for the requested indication AND 4. If the requested agent contains tramadol, dihydrocodeine, or codeine, then ONE of the following: A. The patient is 12 to less than 18 years of age AND the requested opioid will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy OR B. The patient is 18 years of age or over Length of Approval: 1 month for dose titration requests and up to 6 months for all other requests