BlueCross BlueShield of Illinois
BlueCross BlueShield of Montana
BlueCross BlueShield of New Mexico
BlueCross BlueShield of Oklahoma
BlueCross BlueShield of Texas

Opioids, Extended Release (ER) Quantity Limit Criteria

This program is implemented for IL, NM, and TX Medicaid.

NOTE: Quantity Limit for Xtampza ER will be 4 tablets daily for TX Medicaid.

FDA APPROVED INDICATIONS AND DOSAGE

FDA-Approved Indications:[1-6,10,14-16,18-22,24,25]
Narcotic analgesics are indicated for relief of moderate to severe pain.

Brand/Generic Name	Strength	Dosing frequency (maximum labeled dose[a])
Narcotics		
Arymo ER™ (morphine sulfate ER)	15, 30, 60 mg	Two to three times daily
Avinza morphine sulfate ER	30, 45, 60, 75, 90, 120 mg	Once daily (not to exceed 1600 mg daily)
Belbuca™ (buprenorphine buccal film)	75, 150, 300, 450, 600, 750, 900 mcg	Twice daily (not to exceed 900 mcg twice daily)
Butrans Buprenorphine Transdermal System	5, 7.5, 10, 15, 20 mcg/hour system	1 transdermal system weekly (maximum dose 20 mcg/hr)
Duragesic (fentanyl transdermal patch ER)	12, 25, 50, 75, 100 mcg/hour	15 patches / month
Embeda (morphine/naltrexone ER)	20-0.8, 30-1.2, 50-2, 60-2.4, 80-3.2, 100-4 mg	Once or twice daily
Exalgo (hydromorphone ER)	8, 12, 16, 32 mg	Once daily
Fentanyl transdermal patch	37.5, 62.5, 87.5 mcg/hour	15 patches / month
Hysingla ER (hydrocodone ER)	20, 30, 40, 60, 80, 100, 120 mg	Once daily
Kadian (morphine ER)	10, 20, 30, 40, 50, 60, 70, 80, 100, 130, 150, 200 mg	Once or twice daily
Morphabond ER (morphine ER)	15, 30, 60, 100 mg	Twice daily
MS Contin (morphine sulfate ER)	15, 30, 60, 100, 200 mg	Twice daily (some patients may require three times daily)
Opana ER (oxymorphone ER)	5, 7.5, 10, 15, 20, 30, 40 mg	Twice daily
Opana ER crush-resistant (oxymorphone ER)	5, 7.5, 10, 15, 20, 30, 40 mg	Twice daily
Oramorph SR (morphine ER)	15, 30, 60, 100 mg	Twice daily (some patients may require three times daily)
OxyContin (oxycodone ER)	10, 15, 20, 30, 40, 60, 80 mg	Twice daily
Xartemis XR	7.5/325 mg	Twice daily

Brand/Generic Name	Strength	Dosing frequency (maximum labeled dose[a])
(oxycodone and acetaminophen ER)		
Xtampza ER (oxycodone ER)	9, 13.5, 18, 27, 36 mg	Twice daily (288 mg)
Zohydro ER (hydrocodone ER)	10, 15, 20, 30, 40, 50 mg	Twice daily
Zohydro ER Abuse Deterrent (hydrocodone ER)	10, 15, 20, 30, 40, 50 mg	Twice daily
Tramadol, Tapentadol		
Conzip (tramadol SR biphasic)	100, 200, 300 mg	Once daily
Nucynta ER (tapentadol ER)	50, 100, 150, 200, 250 mg	Twice daily
Ryzolt (tramadol extended-release)	100, 200, 300 mg	Once daily
Tramadol SR Biphasic (tramadol SR biphasic)	150 mg	Once daily
Ultram ER (tramadol extended-release)	100, 200, 300 mg	Once daily

a - Maximum dosage units in FDA-approved labeling where available. In addition, daily doses should not exceed the following limits for individual ingredients: tramadol ER - 300 mg, tapentadol ER - 500 mg

CLINICAL RATIONALE[1,2]
Narcotic analgesics and combinations are indicated for the treatment of mild to moderate to severe pain. Immediate release products may be administered on an as needed basis whereas extended release agents are used in the treatment of chronic pain. Morphine remains the prototype opioid; as newer agents are introduced, their efficacy and safety are compared to morphine as the gold standard. Morphine is considered the drug of choice for severe pain[3] There is insufficient evidence to recommend any alternative opioid in preference to morphine as the opioid of first choice.[9] Tramadol has been found to be efficacious in several randomized trials for the treatment of neuropathic pain, chronic non-cancer pain, and osteoarthritis pain.[10]

Current Guidelines
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. Three days or less will often be sufficient; more than seven days will rarely be needed.[23]

When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. 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.[23]

Scientific research has identified high-risk prescribing practices that have contributed to the overdose epidemic (e.g., high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting [ER/LA] opioids for acute pain).[23]

The National Comprehensive Cancer Network (NCCN) Guidelines: Adult Cancer Pain 2015

include the following recommendations:[5]

- In a patient who has not been exposed to opioids in the past morphine is generally considered the standard starting drug of choice. Oral administration is the preferred route. Patients presenting with severe pain needed urgent relief should be treated with parenteral opioids (Category 1).

Category 1= Recommendation based on high level evidence (ie., randomized trials) and there is uniform NCCN consensus. Category 2A = Recommendation based on lower level evidence and there is uniform NCCN consensus.

The Evidence-based Guideline: Treatment of painful diabetic neuropathy (DPN) from the American Academy of Neurology (AAN), the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation state the following:[11] Dextromethorphan, morphine, tramadol, and oxycodone should be considered for the treatment of DPN, but data is insufficient to recommend one agent over the other, but are not considered as first line therapy.[11] Tapentadol has a similar mechanism of action as tramadol, with indications for treatment of moderate to severe pain in adults as well as for the treatment of diabetic peripheral neuropathy, but is not recommended by any guidelines.[2,11]

The World Health Organization (WHO) Pain Relief Ladder states:[6]
If pain occurs, there should be prompt oral administration of drugs in the following order: nonopioids (aspirin and acetaminophen); then, as necessary, mild opioids (codeine); then strong opioids such as morphine, until the patient is free of pain.

The American Society for Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain (2012) states the following: While there is significant short-term evidence available for all opioids, the evidence for long-term effectiveness is inconclusive due to relatively short (3 months) duration of studies and lack of quality studies[13]

Safety
Adverse effects to opioid analgesics include respiratory depression, nausea, vomiting, urinary retention, mental clouding, tolerance and dependence, sedation, ileus, constipation, euphoria, pruritus, and biliary spasms.

Patients should receive FDA approved dosing as excessive narcotic administration may lead to coma or death. Patients that develop opioid tolerance may need increased doses or additional therapies to manage pain. Tramadol and tramadol containing products have been associated with adverse events including seizures that may be dose related.[1,2]

In September 2013, the FDA issued a safety bulletin. In an effort to combat the rising rate of opioid-related deaths, the FDA will require safety label changes on all extended release and long-acting opioid analgesics (extended-release and long-acting opioids include hydromorphone, morphine, oxycodone, oxymorphone, and tapentadol).[12]

- The new safety information will emphasize that the drugs are only to be used for patients requiring continuous treatment when other treatment options, including non-opioid analgesics or immediate-release opioids, are ineffective or intolerable. The labels will also indicate that the drugs should not be used on an "as-needed" pain relief basis.
- The FDA is also requiring a new boxed warning on ER/LA opioid analgesics to caution that chronic maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require management according to protocols developed by neonatology experts.

- In addition, the FDA is notifying ER/LA opioid analgesic application holders of the need for changes to the following sections of drug labeling: Dosage and Administration; Warnings and Precautions; Drug Interactions; Use in Specific Populations; Patient Counseling Information, and the Medication Guide.[12]
- Once the safety labeling changes are finalized, modifications will also be made to the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS), to reflect the updated information.
- The FDA will also require drug companies to conduct longer studies and trials of extended-release and long-acting opioid painkillers that are already on the market. The studies will assess known risks associated with the drugs, including increased sensitivity to pain, misuse, abuse, addiction, overdose, and death.[12]

Hydrocodone combination products have been reclassified to Schedule II by the Drug Enforcement Administration (DEA) effective October 2014. This change followed the recommendation out of the FDA Advisory Committee meeting that occurred in January 2013 where the committee voted 19 to 10 to reschedule these products.[17]

Concomitant use of tramadol with MAO inhibitors or selective serotonin reuptake inhibitors (SSRIs) increases the risk of adverse events such as seizures and serotonin syndrome. Withdrawal symptoms may occur if tramadol is discontinued abruptly.[10]

For additional clinical information see the Prime Therapeutics Formulary Chapters 10.1: Non-Narcotic Analgesics; 10.2A: Narcotic Agonists + Mixed; 10.2B: Tramadol; 10.2C: Narcotic Combinations; and Prime Therapeutics Formulary Monograph: Nucynta (tapentadol)

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Document History – Pain QL

Original Prime Standard criteria approved by P&T UM Committee 05/2010
Administrative Action (addition of Rybix ODT) 07/2010
Administrative Action (addition of Cocet Plus) 10/2010
Annual Review Prime Standard criteria with changes approved by P&T UM Committee 01/2011
Administrative Action (addition of Xodol generic) 02/2011
Administrative Action (revision oxycodone/ASA GPI; addition of product Orbivan with QL of 6/day; addition of Hycet generic, addition of Nucynta ER and Conzip) 09/2011
Annual Review Prime Standard criteria, with changes, approved by P&T UM Committee 01/2012
Administrative Action (addition of generic tramadol SR biphasic release, for Ryzolt) 02/2012
Administrative Action (deletion of oxycodone 5/ASA 325; addition of new GPIs for Opana ER crush-resistant; revision of GPI for Rybix) 03/2012
Administrative Action (addition of Orbivan CF and butalbital 50/APAP 650; addition of tramadol SR biphasic 150 mg; addition hydrocodone 2.5/APAP 325) 05/2012
Administrative Action (deletion of Magnacet 2.5/400, Margesic-H, Panlor DC, obsolete products; addition Hydrogesic and Polygesic, Endocet with footnote and Endodan; removal footnote for generics of APAP/caffeine/dihydrocodeine products and oxymorphone SR 7.5, 15mg) 07/2012

Document History – Opioids Extended Release (ER) QL

Annual Review Prime Standard criteria with changes approved by P&T UM Committee 10/2012
Administrative Action (added footnote for generic strengths of Kadian) 11/2012
Administrative Action (added Opana ER crush-resistant 7.5 mg and 15 mg strengths) 01/2013
Mid-Year Review Prime Standard criteria (approval duration revised to 6 months) reviewed by P&T UM Committee 01/2013-2
Administrative Action (addition of generic oxymorphone ER 7.5 mg, 15 mg; MedD 2013 module) 01/2013-2
Administrative Action (Medicare Part D: revision textbox, QL grid note, all approval durations 12 months) 06/2013
Administrative Action (revision of morphine sulfate SR GPIs) 06/2013
Administrative Action (addition Butrans 15 mcg/hr; addition generic for Kadian 10mg; addition generic for Oxymorphone SR 10/20/30/40 mg tablets) 09/2013
Annual Review Prime Standard Criteria, with changes, approved by P&T UM Committee 01/2014
Administrative Action (addition of generics for Avinza, GPIs for Zohydro ER) 02/2014
Administrative Action (addition of generics for Exalgo 8 mg, 12 mg, 16 mg tablets) 05/2014
Administrative Action (addition of Butrans 7.5 mcg as program target) 09/14
Mid-Year Review Prime Standard criteria with changes, approved by P&T Committee 10/2014
Administrative Action (addition of Hysingla ER as program target with quantity limit) 12/2014
Annual Review Prime Standard criteria, maintained, approved by P&T UM Committee 01/2015

Administrative Action (addition of Zohydro ER Abuse Deterrent as target) 03/2015
Administrative Action (note inactivation of Avinza and the availability of single source morphine sulfate ER) 06/2015
Mid-Year Review Prime Standard criteria with changes, to be approved by P&T UM Committee 10/2015
Administrative Action (addition of Belbuca as program target) December 2015
Annual Review Prime Standard criteria, with changes, approved by P&T UM Committee 01/2016
Administrative Action (addition of Xtampza ER as target) 05/2016
Mid-Year Review Prime Standard criteria, with changes, approved by P&T UM Committee 07/2016
Annual Review Prime Standard criteria, maintained, approved by P&T UM Committee 01/2017
Administrative Action (addition of Arymo ER as program target) 03/2017
Administrative Action (addition of Morphabond ER as program target, and correction to include Xartemis XR in question set maximum daily dose table) 05/2017
Administrative Action (note availability of branded generic buprenorphine transdermal system) 06/2017

Document History – HCSC Medicaid
Initial client specific review, client specific criteria (requirements of 7 day IR opioid before ER product and opioid tolerance), approved by HCSC Medicaid 01/2018
Administrative Action (note generic availability of fentanyl TD patches) 03/2018
Administrative Action (updated GPI table to remove Nucynta and updated program summary and question set for clarification) 04/2018

Opioids ER Quantity Limit

OBJECTIVE

The intent of the quantity limit for the target agents is to allow for quantities that permit dose choices that individualize the treatment plan for chronic pain to the needs of the patient. Requests for larger quantities will be reviewed if the prescriber provides evidence that the requested dose is appropriate for the patient

QUANTITY LIMIT TARGET DRUGS - RECOMMENDED LIMITS

Brand (generic)	GPI	Quantity Per Day Limit
Narcotic Analgesics		
Arymo ER™ (morphine sulfate)		
15 mg extended release tablet	6510005510A620	3 tablets
30 mg extended release tablet	6510005510A630	3 tablets
60 mg extended release tablet	6510005510A640	3 tablets
Avinza®, morphine sulfate ER		
30 mg sustained-release capsule	65100055207020	1 capsule
45 mg sustained-release capsule	65100055207025	1 capsule
60 mg sustained-release capsule	65100055207030	1 capsule
75 mg sustained-release capsule	65100055207035	1 capsule
90 mg sustained-release capsule	65100055207040	1 capsule
120 mg sustained-release capsule	65100055207050	1 capsule
Belbuca™ (buprenorphine buccal film)		
75 mcg buccal film	65200010108210	2 films
150 mcg buccal film	65200010108220	2 films
300 mcg buccal film	65200010108230	2 films
450 mcg buccal film	65200010108240	2 films
600 mcg buccal film	65200010108250	2 films
750 mcg buccal film	65200010108260	2 films
900 mcg buccal film	65200010108270	2 films
Butrans®, Buprenorphine Transdermal System		
5 mcg/hour transdermal system	65200010008820	1 system/week
7.5 mcg/hour transdermal system	65200010008825	1 system/week
10 mcg/hour transdermal system	65200010008830	1 system/week
15 mcg/hour transdermal system	65200010008835	1 system/week
20 mcg/hour transdermal system	65200010008840	1 system/week
Duragesic® (fentanyl transdermal patch)		
12 mcg/hr transdermal patch	65100025008610	15 patches/month
25 mcg/hr transdermal patch	65100025008620	15 patches/month
50 mcg/hr transdermal patch	65100025008630	15 patches/month
75 mcg/hr transdermal patch	65100025008640	15 patches/month
100 mcg/hr transdermal patch	65100025008650	15 patches/month
Embeda® (morphine/naltrexone)		
20 mg/0.8 mg controlled-release capsule	65100055700220	2 capsules
30 mg/1.2 mg controlled-release capsule	65100055700230	2 capsules
50 mg/2 mg controlled-release capsule	65100055700240	2 capsules
60 mg/2.4 mg controlled-release capsule	65100055700250	2 capsules
80 mg/3.2 mg controlled-release capsule	65100055700260	2 capsules
100 mg/4 mg controlled-release capsule	65100055700270	2 capsules
Exalgo® (hydromorphone)		
8 mg extended-release tablet[a]	6510003510A820	1 tablet
12 mg extended-release tablet[a]	6510003510A830	1 tablet

Brand (generic)	GPI	Quantity Per Day Limit
16 mg extended-release tablet[a]	6510003510A840	1 tablet
32 mg extended-release tablet	6510003510A855	1 tablet
Fentanyl transdermal patch		
37.5 mcg/hr transdermal patch[a]	65100025008626	15 patches/month
62.5 mcg/hr transdermal patch[a]	65100025008635	15 patches/month
87.5 mcg/hr transdermal patch[a]	65100025008645	15 patches/month
Hysingla ER® (hydrocodone)		
20 mg extended-release tablet	6510003010A810	1 tablet
30 mg extended-release tablet	6510003010A820	1 tablet
40 mg extended-release tablet	6510003010A830	1 tablet
60 mg extended-release tablet	6510003010A840	1 tablet
80 mg extended-release tablet	6510003010A850	1 tablet
100 mg extended-release tablet	6510003010A860	1 tablet
120 mg extended-release tablet	6510003010A870	1 tablet
Kadian® (morphine sulfate)		
10 mg sustained-release capsule[a]	65100055107010	2 capsules
20 mg sustained-release capsule[a]	65100055107020	2 capsules
30 mg sustained-release capsule[a]	65100055107030	2 capsules
40 mg sustained-release capsule	65100055107035	2 capsules
50 mg sustained-release capsule[a]	65100055107040	2 capsules
60 mg sustained-release capsule[a]	65100055107045	2 capsules
70 mg sustained-release capsule[b]	65100055107047	2 capsules
80 mg sustained-release capsule[a]	65100055107050	2 capsules
100 mg sustained-release capsule[a]	65100055107060	2 capsules
130 mg sustained-release capsule[b]	65100055107070	2 capsules
150 mg sustained-release capsule[b]	65100055107074	2 capsules
200 mg sustained-release capsule	65100055107080	2 capsules
Morphabond ER™ (morphine ER)		
15 mg ER tablet	6510005510A720	2 tablets
30 mg ER tablet	6510005510A730	2 tablets
60 mg ER tablet	6510005510A740	2 tablets
100 mg ER tablet	6510005510A760	2 tablets
MS Contin® (morphine sulfate)[a]		
15 mg sustained-release tablet[a]	65100055100415	3 tablets
30 mg sustained-release tablet[a]	65100055100432	3 tablets
60 mg sustained-release tablet[a]	65100055100445	3 tablets
100 mg sustained-release tablet[a]	65100055100460	3 tablets
200 mg sustained-release tablet[a]	65100055100480	3 tablets
Opana ER® /oxymorphone SR		
5 mg sustained-release tablet[a]	65100080107405	2 tablets
7.5 mg sustained-release tablet[a]	65100080107407	2 tablets
10 mg sustained-release tablet[a]	65100080107410	2 tablets
15 mg sustained-release tablet[a]	65100080107415	2 tablets
20 mg sustained-release tablet[a]	65100080107420	2 tablets
30 mg sustained-release tablet[a]	65100080107430	2 tablets

Brand (generic)	GPI	Quantity Per Day Limit
40 mg sustained-release tablet[a]	65100080107440	2 tablets
Opana ER® (oxymorphone SR, crush resistant)		
5 mg sustained-release tablet	6510008010A705	2 tablets
7.5 mg sustained-release tablet	6510008010A707	2 tablets
10 mg sustained-release tablet	6510008010A710	2 tablets
15 mg sustained-release tablet	6510008010A715	2 tablets
20 mg sustained-release tablet	6510008010A720	2 tablets
30 mg sustained-release tablet	6510008010A730	2 tablets
40 mg sustained-release tablet	6510008010A740	2 tablets
Oramorph SR® (morphine sulfate)		
15 mg sustained-release tablet[b]	65100055107415	3 tablets
30 mg sustained-release tablet[b]	65100055107430	3 tablets
60 mg sustained-release tablet[b]	65100055107445	3 tablets
100 mg sustained-release tablet[b]	65100055107460	3 tablets
OxyContin® (oxycodone ER)		
10 mg tablet	6510007510A710	4 tablets
15 mg tablet	6510007510A715	4 tablets
20 mg tablet	6510007510A720	4 tablets
30 mg tablet	6510007510A730	4 tablets
40 mg tablet	6510007510A740	4 tablets
60 mg tablet	6510007510A760	4 tablets
80 mg tablet	6510007510A780	4 tablets
Xartemis™ XR (oxycodone/acetaminophen)		
7.5/325 mg tablet	65990002200430	4 tablets
Xtampza ER™ (oxycodone ER)		
9 mg capsule	6510007500A310	2 capsules
13.5 mg capsule	6510007500A315	2 capsules
18 mg capsule	6510007500A320	2 capsules
27 mg capsule	6510007500A330	2 capsules
36 mg capsule	6510007500A340	2 capsules
Zohydro® ER Abuse Deterrent (hydrocodone ER)		
10 mg sustained-release capsule	6510003010A310	2 capsules
15 mg sustained-release capsule	6510003010A315	2 capsules
20 mg sustained-release capsule	6510003010A320	2 capsules
30 mg sustained-release capsule	6510003010A330	2 capsules
40 mg sustained-release capsule	6510003010A340	2 capsules
50 mg sustained-release capsule	6510003010A350	2 capsules
Tramadol, Tapentadol		
ConZip™ (tramadol SR biphasic)		
100 mg sustained-release capsule	65100095107070	1 capsule
200 mg sustained-release capsule	65100095107080	1 capsule
300 mg sustained-release capsule	65100095107090	1 capsule
Nucynta ER® (tapentadol SR)		

Brand (generic)	GPI	Quantity Per Day Limit
50 mg extended-release tablet	65100091107420	2 tablets
100 mg extended-release tablet	65100091107430	2 tablets
150 mg extended-release tablet	65100091107440	2 tablets
200 mg extended-release tablet	65100091107450	2 tablets
250 mg extended-release tablet	65100091107460	2 tablets
tramadol[a]		
100 mg sustained-release tablet[a]	65100095107560	1 tablet
200 mg sustained-release tablet[a]	65100095107570	1 tablet
300 mg sustained-release tablet[a]	65100095107580	1 tablet
Tramadol ER (tramadol SR biphasic)		
150 mg sustained-release capsule	65100095107075	1 capsule
Ultram ER® (tramadol ER)[a]		
100 mg sustained-release tablet	65100095107520	1 tablet
200 mg sustained-release tablet	65100095107530	1 tablet
300 mg sustained-release tablet	65100095107540	1 tablet

a – generic available, included in quantity limit program
b- discontinued

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Quantities of **Opioids ER** which are **greater than the** quantity limit will be approved when BOTH of the following are met:

1. The quantity (dose) requested cannot be achieved using a lesser quantity of a higher strength
   AND
2. ONE of the following:
   a. The member has a diagnosis of active cancer pain due to an active malignancy
      OR
   b. The member is eligible for hospice care
      OR
   c. The member is undergoing treatment of chronic non-cancer pain and ALL of the following are met:
      i. The prescriber provides documentation of a formal, consultative evaluation including:
         a. Diagnosis
            AND
         b. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

      AND

      ii. The prescriber has confirmed that a patient-specific pain management plan is on file for the patient
      AND
      iii. The prescriber has confirmed that the patient is not diverting the requested medication, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable
      AND
      iv. If the requested agent is a long-acting opioid, then BOTH of the following:
         a. If the patient is NOT currently being treated with a long-acting opioid in the past 60 days, then the patient's medication history includes a trial of 7 days or less of an immediate-acting opioid in the past 30 days
            AND
         b. The patient is opioid tolerant, if applicable, according to FDA label

      AND

      v. ONE of the following:
         a. The patient is currently being treated with the requested quantity (dose)
            OR
         b. The patient is not currently being treated with the requested quantity (dose), AND ONE of the following:
            1. The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling AND the dosage increase requested is appropriate based on recommended dosage titrations in FDA labeling or compendia AND the prescriber has submitted documentation in support of therapy for an accepted diagnosis for exception which has been reviewed and approved by the Clinical Review pharmacist
               OR
            2. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling or there is no maximum dose/duration in FDA labeling AND the prescriber has submitted documentation in support of therapy for an excepted diagnosis for exception which has

been reviewed and approved by the Clinical Review pharmacist

AND

vi. A review of the patient's claims history does not indicate a potential risk for misuse

Length of Approval: 1 month for dose titration requests
Up to 6 months for all other requests

Opioids ER Quantity Limit

ELECTRONIC EDIT
The quantity limit edit for Opioid ER medications (GPIs in table above, all multisource codes) allows an automatic approval for patients prescribed quantities at or below the program limits.

PRIOR AUTHORIZATION CRITERIA QUESTION SET
Evaluation

1. Is the quantity requested greater than the set limit?
   If yes, continue to 2. If no, review is not applicable.

2. Can the prescribed dose be achieved with a lesser quantity of a higher strength that does not exceed the set limit?
   If yes, deny. If no, continue to 3.

3. Does the patient have a diagnosis of active cancer pain due to an active malignancy?
   If yes, approve for 1 month for dose titration requests and up to 6 months for all other requests.
   If no, continue to 4.

4. Is the patient eligible for hospice care?
   If yes, approve for 1 month for dose titration requests and up to 6 months for all other requests.
   If no, continue to 5.

5. Is the member undergoing treatment of chronic non-cancer pain?
   If yes, continue to 6.
   If no, deny.

6. Has the prescriber provided documentation of a formal, consultative evaluation including ALL of the following?
   a. Diagnosis **AND**
   b. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy

   If yes, continue to 7.
   If no, deny.

7. Has the prescriber confirmed that a patient-specific pain management plan is on file for the patient?
   If yes, continue to 8.
   If no, deny.

8. Has the prescriber confirmed that the patient is not diverting the requested medication, according to the patient's records in the state's prescription drug monitoring program (PDMP), if applicable?
   If yes, continue to 9.
   If no, deny.

9. Is the request for:
   a. A long-acting opioid
   b. A long-acting pain medication (e.g., tramadol ER (Ultram ER), tapentadol ER (Nucynta ER))

   If a, continue to 10. If b, continue to 14.

10. Is the patient currently treated with a long-acting opioid as indicated by:
    a. evidence of paid claim(s) within the past 60 days
    b. patient is new to the claim system within the past 90 days AND a statement by the prescriber that the patient has been taking the medication long-acting opioid in the past 60 days
    c. no evidence of treatment with a long-acting opioid

    If a or b, continue to 12. If c, continue to 11.

11. Does the patient's medication history include a trial of 7 days or less of an immediate-acting opioid in the last 30 days?
    If yes, continue to 12. If no, deny.

12. Does the FDA label for the requested long-acting opioid require that the patient be opioid tolerant? Refer to the strength, quantity, total dose requested, and the table below.
    If yes, continue to 13. If no, continue to 14.

Brand/Generic Name	Strength	Opioid Tolerant Definition per label
Narcotics		
Arymo ER™ (morphine sulfate ER)	15, 30, 60 mg	Patients who are already receiving and tolerate a single dose greater than 60mg, or a total daily dose of 120mg for one week or longer
Avinza morphine sulfate ER	30, 45, 60, 75, 90, 120 mg	The 45, 60, 75, 90, and 120mg capsules are for use only in opioid-tolerant patients
Belbuca™ (buprenorphine buccal film)	75, 150, 300, 450, 600, 750, 900 mcg	Not available
Butrans Buprenorphine Transdermal System	5, 7.5, 10, 15, 20 mcg/hour system	Doses of 7.5, 10, 15, and 20 mcg/hr are only for patients who are opioid experienced
Duragesic (fentanyl transdermal patch ER)	12, 25, 50, 75, 100 mcg/hour	All strengths are indicated for opioid-tolerant patients
Embeda (morphine/naltrexone ER)	20-0.8, 30-1.2, 50-2, 60-2.4, 80-3.2, 100-4 mg	Patients who are already receiving and tolerate 100 mg/4 mg capsules, a single dose greater than 60 mg/2.4 mg, or a total daily dose greater than 120 mg/5 mg for one week or longer
Exalgo (hydromorphone ER)	8, 12, 16, 32 mg	All strengths are indicated for opioid-tolerant patients
Fentanyl transdermal patch	37.5, 62.5, 87.5 mcg/hour	All strengths are indicated for opioid-tolerant patients
Hysingla ER (hydrocodone ER)	20, 30, 40, 60, 80, 100, 120 mg	Patients who are already receiving and tolerate daily doses of Hysingla ER greater than or equal to 80mg for one week or longer

Brand/Generic Name	Strength	Opioid Tolerant Definition per label
Kadian (morphine ER)	10, 20, 30, 40, 50, 60, 70, 80, 100, 130, 150, 200 mg	100mg, 130mg, 150mg, and 200mg are indicated for opioid-tolerant patients
Morphabond ER (morphine ER)	15, 30, 60, 100 mg	Patients who are already receiving and tolerate 100mg tablets, a single dose greater than 60mg, or a total daily dose of 120mg for one week or longer
MS Contin (morphine sulfate ER)	15, 30, 60, 100, 200 mg	Patients who are already receiving and tolerate 100mg and 200mg capsules, a single dose greater than 60 mg, or a total daily dose of 120 mg for one week or longer
Opana ER (oxymorphone ER)	5, 7.5, 10, 15, 20, 30, 40 mg	Not available
Opana ER crush-resistant (oxymorphone ER)	5, 7.5, 10, 15, 20, 30, 40 mg	Not available
Oramorph SR (morphine ER)	15, 30, 60, 100 mg	Patients who are already receiving and tolerate 100mg tablets, a single dose greater than 60mg, or a total daily dose of 120mg for one week or longer
OxyContin (oxycodone ER)	10, 15, 20, 30, 40, 60, 80 mg	**Adults** who are already receiving and tolerate Oxycontin 60 or 80mg tablets, a single dose greater than 40mg, a total daily dose greater than 80mg **Pediatrics** 11 years of age and older who are already receiving and tolerate a minimum daily dose of at least 20 mg oxycodone orally or its equivalent
Xartemis XR (oxycodone and acetaminophen ER)	7.5/325 mg	Not available
Xtampza ER (oxycodone ER)	9, 13.5, 18, 27, 36 mg	Patients who are already receiving and tolerate a total daily dose greater than 72 mg, a single dose greater than 36 mg for one week or longer

Brand/Generic Name	Strength	Opioid Tolerant Definition per label
Zohydro ER Abuse Deterrent (hydrocodone ER)	10, 15, 20, 30, 40, 50 mg	Patients who are already receiving and tolerate daily doses of Zohydro ER, a single dose greater than 40 mg, or a total daily dose greater than 80 mg for one week or longer
Tramadol, Tapentadol		
Conzip (tramadol SR biphasic)	100, 200, 300 mg	Not available
Nucynta ER (tapentadol ER)	50, 100, 150, 200, 250 mg	Not available
tramadol extended-release	100, 200, 300 mg	Not available
Tramadol SR Biphasic (tramadol SR biphasic)	150 mg	Not available
Ultram ER (tramadol extended-release)	100, 200, 300 mg	Not available

13. Is the patient currently opioid tolerant according to label (refer to table above as a reference, but not all inclusive)?
    If yes, continue to 14.
    If no, deny.

14. Is the patient currently being treated with the requested dose/quantity as evidenced by a paid claim within the past 90 days?
    If yes, continue to 18. If no, continue to 15.

15. Is the quantity requested greater than the maximum quantity recommended in FDA approved labeling or is there no maximum dose/duration in FDA labeling?
    If yes, continue to 17. If no, continue to 16.

16. Is the dosage increase requested appropriate based on recommended dosage titrations in FDA labeling or Compendia (i.e., dosage increase is not excessive; patient has been on current dose a sufficient length of time to determine efficacy/adverse effects)?
    If yes, continue to 17. If no, deny.

17. Has the prescriber submitted documentation in support of therapy for an accepted diagnosis for exception (accepted documentation may include documentation from approved compendia; or if there is no maximum FDA dose or recommended dose for the agent, the pharmacist can accept chart notes indicating benefit if already on requested dose) and has the pharmacist reviewed and addressed any potential issues associated with duplicate therapy?
    If yes, pharmacist must review and based on review of information provided may continue to 18. If no, deny.

18. Does a review of the member's claim history indicate a potential risk of misuse as indicated by:
    a. dose requested is greater than twice the quantity limit of the highest strength of the requested agent OR
    b. more than one extended release formulation being used concurrently OR

c. three or more of the following seen in the members claim history
    i. three or more different narcotic analgesics in any given month within the last 6 months
    ii. three or more rejected refills in any given month within the last 6 months for narcotic analgesics
    iii. three or more early fills for narcotic analgesics when 85% or less days supply has been used i.e. consistent early refills despite there being more than 15% of the last fill in member's possession each time.
    iv. narcotic analgesics filled at three or more pharmacies in the last 6 months
    v. narcotic analgesics prescribed by three or more prescribers in the last 6 months
    vi. three or more dosage increases requested in the past six months

If yes, pharmacist must review and may approve for 1 month for dosage titration requests and up to 3 months for all other requests AND refer to the plan for additional evaluation (email rxcsiprograms@bcbstx.com).
If no, pharmacist must review and may approve quantity requested for 1 month for dosage titration requests and up to 6 months for all other requests (or as indicated under "Allowed exception cases/diagnoses").