Opioids ER Prior Authorization with Quantity Limit

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Belbuca® (buprenorphine) Buccal film	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.		5
Butrans® (buprenorphine) Transdermal patch*	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.	*generic available	6
Conzip®, Tramadol Sustained Release Capsule 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.		7,19
fentanyl Transdermal patch*	Management of pain in opioid tolerant patients, 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	*generic available	10

Agent(s)	FDA Indication(s)	Notes	Ref#
	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.		
hydromorphone Extended-Release Tablet*	Management of pain in opioid tolerant patients 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.	* generic available	9
Hysingla ER® (hydrocodone 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.	*generic available	11
Morphine Sulfate Extended-Release Capsule*	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.	*generic available	12,14
MS Contin® (morphine sulfate 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.	*generic available	15

Agent(s)	FDA Indication(s)	Notes	Ref#
Nucynta ER® (tapentadol Extended-Release) Tablet	Pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults 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 tapentadol ER for use in patients for whom alternative treatment options (e.g., nonopioid 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 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.		17
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 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.		20

Agent(s)	FDA Indication(s)	Notes	Ref#
Hydrocodone Extended-Release Abuse Deterrent Capsule	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.		21

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:
      1. Information has been provided that the patient has been treated with the requested agent within the past 90 days **OR**
      2. The prescriber states the patient has been treated with the requested agent within the past 90 days AND is at risk if therapy is changed **OR**
   B. ALL of the following:
      1. ONE of the following:
         A. The patient has a diagnosis of chronic 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. The requested agent is not prescribed as an as-needed (prn) analgesic **AND**
            3. ONE of the following:
               A. The patient's medication history includes a trial of at least 7 days of an immediate-acting opioid **OR**
               B. The patient has an intolerance or hypersensitivity to therapy with immediate-acting opioids that is not expected to occur with the requested agent **OR**
               C. The patient has an FDA labeled contraindication to ALL immediate-acting opioids that is not expected to occur with the requested agent **AND**
            4. A patient-specific pain management plan is on file for the patient **AND**
            5. 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

Module	Clinical Criteria for Approval
	combinations of opioids and other controlled substances within the patient's records do NOT indicate the patient is at high risk for overdose **AND** 2. ONE of the following: A. The patient is not concurrently using buprenorphine or buprenorphine/naloxone for opioid dependence treatment **OR** B. The prescriber has provided information in support of use of concurrent use of opioids with buprenorphine or buprenorphine/naloxone for opioid dependence treatment **AND** 3. If the client has preferred agent(s), then ONE of the following: A. The requested agent is a preferred agent **OR** B. The patient has tried and had an inadequate response to a preferred agent **OR** C. The patient has an intolerance or hypersensitivity to a preferred agent **OR** D. The patient has an FDA labeled contraindication to ALL preferred agents **AND** 2. 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 agent 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 **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

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 SR (tramadol ER)	300 mg
Fentanyl transdermal patch	100 mcg/hr patch/2 days
Hysingla (hydrocodone ER)	120 mg
Morphine Sulfate ER (generic Kadian)	200 mg
Morphine Sulfate ER	120 mg
MS Contin (morphine sulfate ER)	600 mg
Nucynta ER (tapentadol ER)	500 mg
OxyContin (oxycodone ER)	160 mg
Oxymorphone ER	80 mg
Tramadol ER	300 mg
Xtampza ER (oxycodone ER)	288 mg
Zohydro ER (hydrocodone ER)	100 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) is greater than the program quantity limit AND ONE of the following:

Module	Clinical Criteria for Approval
	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: 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. The prescriber has provided information in support of 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. The prescriber has provided information in support of 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
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) is greater than the program quantity limit AND BOTH of the following: A. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **AND** B. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** 6 months