Prior Authorization Guideline

GL-35952 Opioid Quantity Limit Overrides

Formulary OptumRx

Formulary Note: Approval Date 7/10/2017 **Revision Date** 7/10/2017

Technician Note:
P&T Approval Date: 2/16/2010; P&T Revision Date: 7/12/2011 Note: The Opioid Quantity Limit Override Administrative Guideline should be used for single opioids that do not have an FDA-maximum dose. For opioids with an FDA-maximum dose, such as APAP-containing opioid products, please refer to the standard Quantity Limit Override Administrative Guideline or the drug-specific guideline, if applicable.

1. Criteria

Diagnosis	For Malignant Cancer Pain
Approval Length	5 Year
Guideline Type	Administrative
Approval Criteria **1** In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used: **1.1** Diagnosis of malignant (cancer) pain*	
Notes	Authorization will be issued for long-term therapy. *For oral fentanyl products, please refer to the drug-specific quantity limit override criteria in the “Oral Fentanyl Products” guideline.

Diagnosis	For Non-Malignant Pain
Approval Length	1 Year
Guideline Type	Administrative

Approval Criteria

- In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:
  - Prescribed by a pain specialist or by pain management consultation

    AND

  - The prescriber maintains and provides chart documentation of the patient’s evaluation, including all of the following:
- An appropriate patient medical history and physical examination
- A description of the nature and intensity of the pain
- Documentation of appropriate dose escalation
- Documentation of ongoing, periodic review of the course of opioid therapy
- An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function)
- Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian

GL-45685 Opioid Risk Management

Formulary: OptumRx

Formulary Note: Approval Date **11/29/2018,** Revision Date **11/29/2018**

Technician Note:
P&T Approval Date: 11/16/2017; P&T Revision Date: 02/15/2018; 5/17/2018, 07/18/2018, 08/16/2018, 11/15/2018. **(supplemental) Effective Date:10/17/2018**

1. Criteria

Product Name: Short-Acting Opioids

Diagnosis	Cancer or end-of-life care
Approval Length	12 Month
Guideline Type	Quantity Limit
Approval Criteria **1** Diagnosis of cancer or end of life care	
Notes	Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction.

Product Name: Short-Acting Opioids

Diagnosis	Postoperative Pain Management
Approval Length	14 Day
Guideline Type	Quantity Limit
Approval Criteria **1** Medication is being used to treat postoperative pain **AND** **2** Medication is not being prescribed for pain related to a dental procedure **AND** **3** The dose being prescribed is the dose that the patient was stable on prior to discharge	
Notes	*Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. If criteria is approved patients should be approved for the max daily dose/day supply that the prescription is written for.

Product Name: Short-Acting Opioids

Diagnosis	All Other Diagnoses
Approval Length	6 Month
Guideline Type	Quantity Limit
Approval Criteria **1** Prescriber certifies that there is an active treatment plan that includes but is not limited to a specific treatment objective and the use of other pharmacological and non-pharmacological agents for pain relief as appropriate **AND** **2** Prescriber certifies that there has been an informed consent document signed and an addiction risk assessment has been performed **AND** **3** Prescriber certifies that a written/signed agreement between prescriber and patient addressing issues of prescription management, diversion, and the use of other substances exists	
Notes	Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction. If the prescriber is unable to certify written documentation to meet criterion (2) and/or (3), written or verbal attestation from the provider may be accepted confirming that the prescriber (or prescriber's representative) has verbally addressed criterion (2) and/or (3) with the patient.

Product Name: Opioid Cough Medications

Approval Length	6 Month
Guideline Type	Prior Authorization
Approval Criteria **1** Patient is 18 years of age or older	

Product Name: Opioid Cough Medications*

Diagnosis	Greater than the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*
Approval Length	60 Day
Guideline Type	Quantity Limit
Approval Criteria **1** One of the following: **1.1** Quantity limit override requests must involve an FDA-approved indication **OR** **1.2** Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria **AND**	

2 One of the following: **2.1** The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition **OR** **2.2** If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition **AND** **3** One of the following** **3.1** Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information **OR** **3.2** Higher dose or quantity is supported by one of following compendia: • American Hospital Formulary Service Drug Information • Micromedex DRUGDEX System	
Notes	*This guideline only applies in the absence of a drug-specific quantity limit override guideline. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. **NOTE: Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

Product Name: Opana ER

Approval Length	6 Month
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 Prescriber is aware that Opana ER is being withdrawn from the market due to concerns of significant abuse

AND

2 One of the following: [1]

2.1 All of the following:

2.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

2.1.2 None of the following:

- For use as an as-needed (PRN) analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

2.1.3 One of the following:

2.1.3.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4

week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

2.1.3.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

2.2 All of the following:

2.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

2.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document duration, dose and date of trial)

AND

2.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

2.2.4 One of the following:

2.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

2.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

3 Trial and failure, contraindication or intolerance to at least three preferred products:

- hydromorphone ER
- morphine sulfate ER
- oxymorphone ER
- Embeda
- Oxycontin
- Hysingla ER

Notes	If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name: Opana ER

Approval Length	6 Month
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** Documentation has been provided addressing ALL of the following: • Treatment goals are defined, including estimated duration of treatment • Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention • Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g., Brief Pain Inventory) • Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g., DAST-10) • Rationale for not tapering and discontinuing opioid • Patient has been screened for comorbid mental health conditions • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose	
Notes	If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name: Long Acting Opioids* Arymo ER, brand Kadian, Morphabond ER, Nucynta ER, Xtampza ER, Zohydro ER

Diagnosis	Cancer or End-of-Life Care
Approval Length	12 Month
Guideline Type	Prior Authorization
Approval Criteria **1** One of the following: **1.1** Diagnosis of cancer **OR** **1.2** Patient is receiving opioids as part of end-of-life care **AND** **2** Trial and failure, contraindication or intolerance to at least two of the following preferred products • Hydromorphone ER • Morphine sulfate ER • Oxymorphone ER • Embeda • Hysingla ER • Oxycontin	
Notes	*Prior authorization may not apply depending on the plan. If the member is currently taking the requested non-preferred long-acting opioid (OR was recently switched from another long-acting opioid) for cancer-related pain or end-of-life care and has not tried a preferred long-acting opioid, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to a preferred long-acting opioid.

Product Name: Long Acting Opioids: Arymo ER, brand Kadian, Morphabond ER, Nucynta ER, Xtampza ER, Zohydro ER

Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 Month
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 One of the following:

1.1 All of the following:

1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

1.1.2 None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

1.1.3 One of the following:

1.1.3.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.1.3.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy **AND** 2 Trial and failure, contraindication or intolerance to at least two of the following preferred products • Hydromorphone ER • Morphine sulfate ER • Oxymorphone ER • Embeda • Hysingla ER • Oxycontin	
Notes	If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name: Long Acting Opioids: Arymo ER, brand Kadian, Morphabond ER, Nucynta ER, Xtampza ER, Zohydro ER

Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 Month
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** Documentation has been provided addressing ALL of the following • Treatment goals are defined, including estimated duration of treatment • Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention • Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g., Brief Pain Inventory) • Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g., DAST-10) • Rationale for not tapering and discontinuing • Patient has been screened for comorbid mental health • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose	
Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name: Long Acting Opioids: brand DURAGESIC, generic transdermal fentanyl patches, brand DOLOPHINE 5 mg tablets, brand DOLOPHINE 10 mg tablets, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand EXALGO, generic hydromorphone ER, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, EMBEDA, HYSINGLA ER, OXYCONTIN, generic oxycodone ER

Diagnosis	Cancer or End-of-Life Care
Approval Length	12 Month
Guideline Type	Prior Authorization
Approval Criteria **1** One of the following: **1.1** Diagnosis of cancer **OR** **1.2** Patient is receiving opioids as part of end-of-life care	
Notes	*Prior authorization may not apply depending on the plan

Product Name: Long Acting Opioids: brand DURAGESIC, generic transdermal fentanyl patches, brand DOLOPHINE 5 mg tablets, brand DOLOPHINE 10 mg tablets, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand EXALGO, generic hydromorphone ER, Brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, EMBEDA, HYSINGLA ER, OXYCONTIN, generic oxycodone ER

Diagnosis	Non-Cancer/End of Life Care Diagnosis
Approval Length	6 Month
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** One of the following: **1.1** All of the following: **1.1.1** Patient has moderate to severe chronic pain that is non-neuropathic **AND** **1.1.2** None of the following:	
• For use as an as-needed PRN analgesic • For pain that is mild or not expected to persist for an extended period of time • For acute pain • For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time	
AND **1.1.3** One of the following: **1.1.3.1** For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]	

OR

1.1.3.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

Notes	If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name: Long Acting Opioids: brand DURAGESIC, generic transdermal fentanyl patches, brand DOLOPHINE 5 mg tablets, brand DOLOPHINE 10 mg tablets, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand EXALGO, generic hydromorphone ER, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, EMBEDA, HYSINGLA ER, OXYCONTIN, generic oxycodone ER

Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 Month
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** Documentation has been provided addressing ALL of the following: • Treatment goals are defined, including estimated duration of treatment • Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention • Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory) • Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10) • Rationale for not tapering and discontinuing opioid • Patient has been screened for comorbid mental health conditions • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose	
Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name: Brand Butrans, generic buprenorphine patch, Belbuca*

Diagnosis	Cancer or End-of-Life Care
Approval Length	12 Month
Guideline Type	Prior Authorization
Approval Criteria **1** Patient is being treated for cancer related pain or pain associated with end-of-life	
Notes	*Prior authorization may not apply depending on the plan

Product Name: Brand Butrans, generic buprenorphine patch, Belbuca*

Diagnosis	Non- Cancer Pain
Approval Length	6 Month
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment **AND** **2** None of the following: • For use as an as-needed PRN analgesic • For pain that is mild or not expected to persist for an extended period of time • For acute pain • For opioid dependence **AND** **3** The patient is not receiving other long-acting opioids concurrently	
Notes	*Prior authorization may not apply depending on the plan. If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

Product Name: Brand Butrans, generic buprenorphine patch, Belbuca*

Diagnosis	Non-Cancer Pain
Approval Length	6 Month
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** Documentation has been provided addressing ALL of the following • Treatment goals are defined, including estimated duration of treatment • Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention • Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory) • Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10) • Rationale for not tapering and discontinuing opioid • Patient has been screened for comorbid mental health conditions • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose	
Notes	*Prior authorization may not apply depending on the plan. If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to an alternative treatment.

2 . References

1. Opana ER Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. July 2012