



## MEDICATION POLICY

**Generic Name:** Non-Preferred Extended-Release Opioid Analgesics

**Therapeutic Class or Brand Name:** Non-Preferred Extended-Release Opioid Analgesics

**Applicable Drugs** (if Therapeutic Class):

Embeda® (morphine/naltrexone), Exalgo® (hydromorphone), Hysingla® ER (hydrocodone), Kadian® (morphine), MS Contin® (morphine), Nucynta® ER (tapentadol), Opana® ER (oxymorphone), Troxyca® ER (oxycodone/naltrexone), Xtampza™ ER (oxycodone), and Zohydro® ER (hydrocodone).

Policy also applies to any other non-preferred extended-release opioid analgesics not listed.

**Date of Origin:** 2/1/13

**Date Last Reviewed/Revised:** 9/12/16

**GPI Code:** 6510003010A3, 6510003010A8, 6510003510A8, 651000551004, 651000551070, 651000557002, 6510007500A3, 6510008010A7, 651000911074

### **Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):**

- I. Patient has been approved for chronic opioid therapy as outlined in the Chronic Opioid Medication Policy.
- II. Documented trial and failure of, or contraindication to, at least two preferred long-acting narcotics. Must include the names of the preferred products tried or contraindicated, length of therapy, and reason for discontinuation.
- III. Minimum age requirement: 18 years old.

### **Exclusion Criteria:**

- Significant respiratory depression.
- Acute or severe bronchial asthma.
- Known or suspected paralytic ileus.

### **Other Criteria:**

- N/A

### **Quantity/Days Supply Restrictions:**

- The quantity is limited to a maximum of a 30 day supply per fill.

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### Approval Length:

- **Authorization:** Up to 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is providing satisfactory pain control.

### Appendix:

N/A

### References:

1. [http://health.utah.gov/prescription/pdf/policy\\_pdf/bluecrossPositionSummaryOxyContin.pdf](http://health.utah.gov/prescription/pdf/policy_pdf/bluecrossPositionSummaryOxyContin.pdf).
2. <http://blue.regence.com/trgmedpol/drugs/dru142.pdf>.
3. [http://www.fdhc.state.fl.us/medicaid/prescribed\\_drug/pharm\\_thera/paforms/Oxycodone\\_ER\\_Oxycontin\\_Form.pdf](http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Oxycodone_ER_Oxycontin_Form.pdf).
4. [Medi-Span.](#)
5. <http://www.mallinckrodt.com/WorkArea/DownloadAsset.aspx?id=2147483728>.
6. [http://kadian.com/NR/rdonlyres/E24358B1-072D-46B6-B3E2-619A6D6414BA/0/KadianPI\\_424.pdf](http://kadian.com/NR/rdonlyres/E24358B1-072D-46B6-B3E2-619A6D6414BA/0/KadianPI_424.pdf).
7. <http://www.nucynta.com/assets/pdf/nucyntaer-pi.pdf>.
8. [http://www.endo.com/File%20Library/Products/Prescribing%20Information/OpanaER\\_prescribing\\_information\\_newformulation.html](http://www.endo.com/File%20Library/Products/Prescribing%20Information/OpanaER_prescribing_information_newformulation.html).
9. <http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o>.
10. <http://labeling.pfizer.com/showlabeling.aspx?id=694>.
11. <http://app.purduepharma.com/xmlpublishing/pi.aspx?id=h>.
12. <http://app.purduepharma.com/xmlpublishing/pi.aspx?id=ms>.
13. <http://www.zohydroer.com/downloads/ZOHYDROERFullPrescribingInformation.pdf>.
14. <http://www.xtampzaer.com/pdf/xtampza-pi.pdf>.
15. <http://labeling.pfizer.com/ShowLabeling.aspx?id=4047>.

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<b>Historical Tracking Of Changes Made To Policy</b>	
9/12/2016	<ol style="list-style-type: none"> <li>1. <b>Added</b> “Troxyca® ER (oxycodone/naltrexone)” <b>under Applicable Drugs.</b></li> <li>2. <b>Added</b> “<a href="http://labeling.pfizer.com/ShowLabeling.aspx?id=4047">http://labeling.pfizer.com/ShowLabeling.aspx?id=4047</a>” <b>under References.</b></li> </ol>
8/29/2016	<ol style="list-style-type: none"> <li>1. <b>Added</b> “Xtampza™ ER (oxycodone)” <b>under Applicable Drugs.</b></li> <li>2. <b>Added</b> “6510007500A3” <b>following GPI Code.</b></li> <li>3. <b>Added</b> “<a href="http://www.xtampzaer.com/pdf/xtampza-pi.pdf">http://www.xtampzaer.com/pdf/xtampza-pi.pdf</a>” <b>under References.</b></li> </ol>
7/31/2015	<ol style="list-style-type: none"> <li>1. <b>Added</b> “Embeda® (morphine/naltrexone)”, “Hysingla® ER (hydrocodone)”, “MS Contin® (morphine)”, “Opana® ER (oxymorphone)”, <b>and</b> “Zohydro® ER (hydrocodone)” <b>to Applicable Drugs.</b></li> <li>2. <b>Changed GPI Code from</b> “6510003510, 6510005510, 6510009110” <b>to</b> “6510003010A3, 6510003010A8, 6510003510A8, 651000551004, 651000551070, 651000557002, 6510008010A7, 651000911074”.</li> <li>3. <b>Changed</b> “I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. The patient has a diagnosis of cancer, is enrolled in a hospice program, or meets hospice criteria; B. The patient is undergoing treatment of a chronic moderate to severe non-cancer pain. Provider must submit the following documents 1 through 2: 1. A written treatment plan including goals used to determine treatment successes; 2. An opioid treatment agreement signed by the prescribing physician and patient” <b>and</b> “III. The patient requires continuous or around the clock analgesia for an extended period of time” <b>to</b> “I. Patient has been approved for chronic opioid therapy as outlined in the Chronic Opioid Medication Policy” <b>under Prior Authorization Criteria.</b></li> <li>4. <b>Changed Exclusion Criteria from</b> “N/A” <b>to</b> “Significant respiratory depression; Acute or severe bronchial asthma; Known or suspected paralytic ileus”.</li> <li>5. <b>Changed</b> “Avinza®: Quantities of up to 30 capsules per 30 days; Exalgo®: Quantities of up to 60 tablets per 30 days; Kadian®: Quantities of up to 60 capsules per 30 days; Nucynta® ER: Quantities of up to 60 tablets per 30 days; Opana® ER: Quantities of up to 60 tablets per 30 days; OxyContin®: Quantities of up to 60 tablets per 30 days; Quantity limits may be overridden if the prescriber provides a valid ICD-9 diagnosis code for terminal cancer” <b>to</b> “The quantity is limited to a maximum of a 30 day supply per fill” <b>under Quantity/Days Supply Restrictions.</b></li> <li>6. <b>Changed Authorization under Approval Length from</b> “1 year” <b>to</b> “Up to 6 months”.</li> <li>7. <b>Updated</b>  “<a href="http://www.fdhc.state.fl.us/medicaid/Prescribed_Drug/drug_criteria_pdf/FL_PA_Oxycodone_ER_Oxycontin_Form(101712).pdf">http://www.fdhc.state.fl.us/medicaid/Prescribed_Drug/drug_criteria_pdf/FL_PA_Oxycodone_ER_Oxycontin_Form(101712).pdf</a>” <b>to</b>  “<a href="http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Oxycodone_ER_Oxycontin_Form.pdf">http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Oxycodone_ER_Oxycontin_Form.pdf</a>”, “<a href="http://www.exalgo.com/media/pdf/EXALGO_FullPrescribingInformation.pdf">http://www.exalgo.com/media/pdf/EXALGO_FullPrescribingInformation.pdf</a>” <b>to</b>  “<a href="http://www.mallinckrodt.com/WorkArea/DownloadAsset.aspx?id=2147483728">http://www.mallinckrodt.com/WorkArea/DownloadAsset.aspx?id=2147483728</a>”,  “<a href="http://www.kadian.com/NR/rdonlyres/7503AA98-0505-4499-BB8F-0AF444188767/0/KadianPIallstrengthsJuly2012.pdf">http://www.kadian.com/NR/rdonlyres/7503AA98-0505-4499-BB8F-0AF444188767/0/KadianPIallstrengthsJuly2012.pdf</a>” <b>to</b> “<a href="http://kadian.com/NR/rdonlyres/E24358B1-072D-46B6-B3E2-619A6D6414BA/0/KadianPI_424.pdf">http://kadian.com/NR/rdonlyres/E24358B1-072D-46B6-B3E2-619A6D6414BA/0/KadianPI_424.pdf</a>”,  “<a href="http://www.nucynta.com/sites/default/files/pdf/nucyntaer-pi.pdf#zoom=100">http://www.nucynta.com/sites/default/files/pdf/nucyntaer-pi.pdf#zoom=100</a>” <b>to</b>  “<a href="http://www.nucynta.com/_assets/pdf/nucyntaer-pi.pdf">http://www.nucynta.com/_assets/pdf/nucyntaer-pi.pdf</a>”,  “<a href="http://www.endo.com/File%20Library/Products/Prescribing%20Information/OpanaER_Biconcave__prescribing_information-html.html">http://www.endo.com/File%20Library/Products/Prescribing%20Information/OpanaER_Biconcave__prescribing_information-html.html</a>” <b>to</b>  “<a href="http://www.endo.com/File%20Library/Products/Prescribing%20Information/OpanaER_prescribing_information_newformulation.html">http://www.endo.com/File%20Library/Products/Prescribing%20Information/OpanaER_prescribing_information_newformulation.html</a>”, <b>and</b> “<a href="http://www.purduepharma.com/pressroom/news/oxycontinpi.pdf">http://www.purduepharma.com/pressroom/news/oxycontinpi.pdf</a>” <b>to</b> “<a href="http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o">http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o</a>” <b>under References.</b></li> <li>8. <b>Removed</b> “<a href="http://labeling.pfizer.com/ShowLabeling.aspx?id=876">http://labeling.pfizer.com/ShowLabeling.aspx?id=876</a>” <b>from References</b> (product no longer available).</li> <li>9. <b>Added</b> “<a href="http://labeling.pfizer.com/showlabeling.aspx?id=694">http://labeling.pfizer.com/showlabeling.aspx?id=694</a>”,  “<a href="http://app.purduepharma.com/xmlpublishing/pi.aspx?id=h">http://app.purduepharma.com/xmlpublishing/pi.aspx?id=h</a>”,  “<a href="http://app.purduepharma.com/xmlpublishing/pi.aspx?id=ms">http://app.purduepharma.com/xmlpublishing/pi.aspx?id=ms</a>”, <b>and</b></li> </ol>

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<b>Historical Tracking Of Changes Made To Policy</b>	
	“ <a href="http://www.zohydroer.com/downloads/ZOHYDROERFullPrescribingInformation.pdf">http://www.zohydroer.com/downloads/ZOHYDROERFullPrescribingInformation.pdf</a> ” <b>under References.</b>
2/11/2014	<ol style="list-style-type: none"> <li>1. <b>Adapted policy to new format.</b></li> <li>2. <b>Added “Exalgo® (hydromorphone)” to Applicable Drugs.</b></li> <li>3. <b>Removed “Avinza® (morphine), Opana® ER (oxymorphone), and OxyContin® (oxycodone)” from Applicable Drugs list.</b></li> <li>4. <b>Added GPI Codes.</b></li> <li>5. <b>Changed Prior Authorization Criteria from:</b>            “Documented trial and failure of, or contraindication to, at least two preferred long-acting narcotics. Must include the names of the preferred products tried or contraindicated, length of therapy, and reason for discontinuation; AND The patient requires continuous or around the clock analgesia for an extended period of time; AND The patient has a diagnosis of cancer, is enrolled in a hospice program, or meets hospice criteria; OR The patient is undergoing treatment of a chronic moderate to severe non-cancer pain. Provider must submit (1) a written treatment plan including goals used to determine treatment successes AND (2) an opioid treatment agreement signed by the prescribing physician and patient”  <b>to:</b>            “May be considered medically necessary when criteria I through IV are met: I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. The patient has a diagnosis of cancer, is enrolled in a hospice program, or meets hospice criteria; B. The patient is undergoing treatment of a chronic moderate to severe non-cancer pain. Provider must submit the following documents 1 through 2: 1. A written treatment plan including goals used to determine treatment successes; 2. An opioid treatment agreement signed by the prescribing physician and patient; II. Documented trial and failure of, or contraindication to, at least two preferred long-acting narcotics. Must include the names of the preferred products tried or contraindicated, length of therapy, and reason for discontinuation; III. The patient requires continuous or around the clock analgesia for an extended period of time; IV. Minimum age requirement: 18 years old”.</li> <li>6. <b>Added “Exalgo®: Quantities of up to 60 tablets per 30 days”, and added “Quantities of up to” in front of quantities of other products listed under Quantity/Days Supply Restrictions.</b></li> <li>7. <b>Updated references</b> to include Medi-Span and package inserts.</li> </ol>

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