MEDICATION POLICY:

Non-Preferred Extended-Release Opioid Analgesics

Generic Name: Non-Preferred Extended-Release Opioid Analgesics

pplicable Drugs (if Therapeutic Class): Non-Preferred Extended-Release Opioid Analgesics

GPI Code: 6510003010A3, 6510003510A8, 6510005510A6, 6510005510A7, 651000551004, 651000551070, 651000557002, 6510007500A3, 6510008010A7, 651000911074

Preferred: N/A

Non-preferred:

Non-preferred: Arymo® ER (morphine), Embeda® (morphine/naltrexone), Exalgo® (hydromorphone), Kadian® (morphine), MS Contin® (morphine), MorphaBond™ ER (morphine), Nucynta® ER (tapentadol), Xtampza™ ER (oxycodone), and Zohydro® ER (hydrocodone).

Not Medically Necessary: Opana® ER (oxymorphone).

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

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 8/10/2018

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 gastrointestinal obstruction, including paralytic ileus.
- Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days.
- Opana® ER is considered not medically necessary.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

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

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 .
2. http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Oxycodone_ER_Oxycontin_Form.pdf .
3. Medi-Span®.
4. http://www.mallinckrodt.com/WorkArea/DownloadAsset.aspx?id=2147483728 .
5. https://www.allergan.com/assets/pdf/kadian_pi .
6. http://www.nucynta.com/_assets/pdf/nucyntaer-pi.pdf .
7. http://www.endo.com/File%20Library/Products/Prescribing%20Information/OpanaER_prescribing_information_newformulation.html .
8. http://app.purduepharma.com/xmlpublishing/pi.aspx?id=ms .
9. http://www.zohydroer.com/downloads/ZOHYDROERFullPrescribingInformation.pdf.
10. http://www.xtampzaer.com/hcp/assets/pdf/xtampza-pi.pdf .
11. http://labeling.pfizer.com/ShowLabeling.aspx?id=4047 .
12. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e60552c9-06ce-4790-95e7-aadd4df12b2a .
13. https://morphabondhcp.com/prescribing-information-portlet/getDocument?product=MB&inline=true .
14. https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm600788.htm .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
8/10/2018	1. **Removed** All references to Troxyca® ER (product discontinued) 2. **Added** reference item for list of FDA-approved abuse-deterrent opioid products: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm600788.htm 3. **Removed** obsolete URL in reference items #9 http://labeling.pfizer.com/showlabeling.aspx?id=694 and #13 http://labeling.pfizer.com/ShowLabeling.aspx?id=4047 and #2 http://blue.regence.com/trgmedpol/drugs/dru142.pdf .
11/28/2017	1. **Changed** "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" **to** "Non-preferred: Arymo® ER (morphine), Embeda® (morphine/naltrexone), Exalgo® (hydromorphone), Kadian® (morphine), MS Contin® (morphine), MorphaBond™ ER (morphine), Nucynta® ER (tapentadol), Troxyca® ER (oxycodone/naltrexone), Xtampza™ ER (oxycodone), and Zohydro® ER (hydrocodone); Not Medically Necessary: Opana® ER (oxymorphone); Policy also applies to any other non-preferred extended-release opioid analgesics not listed" **under Applicable Drugs**. 2. **Added** "6510005510A6" and "6510005510A7" **following GPI Code**. 3. **Removed** "6510003010A8" **following GPI Code**. 4. **Changed** "Known or suspected paralytic ileus" to "Known or suspected gastrointestinal obstruction, including paralytic ileus" under **Exclusion Criteria**. 5. **Added** "Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days" and "Opana® ER is considered not medically necessary" **under Exclusion Criteria**. 6. **Added** "https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e60552c9-06ce-4790-95e7-aadd4df12b2a" and "https://morphabondhcp.com/prescribing-information-portlet/getDocument?product=MB&inline=true" **under References**. 7. **Updated** "http://kadian.com/NR/rdonlyres/E24358B1-072D-46B6-B3E2-619A6D6414BA/0/KadianPI_424.pdf" to "https://www.allergan.com/assets/pdf/kadian_pi" and "http://www.xtampzaer.com/pdf/xtampza-pi.pdf" to "http://www.xtampzaer.com/hcp/assets/pdf/xtampza-pi.pdf" **under References**. 8. **Removed** "http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o" and "http://app.purduepharma.com/xmlpublishing/pi.aspx?id=h" from **under References**.
9/12/2016	1. **Added** "Troxyca® ER (oxycodone/naltrexone)" **under Applicable Drugs**. 2. **Added** "http://labeling.pfizer.com/ShowLabeling.aspx?id=4047" **under References**.

8/29/2016	1. **Added** "Xtampza™ ER (oxycodone)" **under Applicable Drugs.** 2. **Added** "6510007500A3" **following GPI Code.** 3. **Added** "http://www.xtampzaer.com/pdf/xtampza-pi.pdf" **under References.**
7/31/2015	1. **Added** "Embeda® (morphine/naltrexone)", "Hysingla® ER (hydrocodone)", "MS Contin® (morphine)", "Opana® ER (oxymorphone)", **and** "Zohydro® ER (hydrocodone" **to Applicable Drugs**. 2. **Changed GPI Code from** "6510003510, 6510005510, 6510009110" **to** "6510003010A3, 6510003010A8, 6510003510A8, 651000551004, 651000551070, 651000557002, 6510008010A7, 651000911074". 3. **Changed** "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" **and** "III. The patient requires continuous or around the clock analgesia for an extended period of time" **to** "I. Patient has been approved for chronic opioid therapy as outlined in the Chronic Opioid Medication Policy" **under Prior Authorization Criteria**. 4. **Changed Exclusion Criteria from** "N/A" **to** "Significant respiratory depression; Acute or severe bronchial asthma; Known or suspected paralytic ileus". 5. **Changed** "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" **to** "The quantity is limited to a maximum of a 30 day supply per fill" **under Quantity/Days Supply Restrictions**. 6. **Changed Authorization under Approval Length from** "1 year" **to** "Up to 6 months". 7. **Updated** "http://www.fdhc.state.fl.us/medicaid/Prescribed_Drug/drug_creteria_pdf/FL_PA_Oxycodone_ER_Oxycontin_Form(101712).pdf" **to** "http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pharm_thera/paforms/Oxycodone_ER_Oxycontin_Form.pdf", "http://www.exalgo.com/media/pdf/EXALGO_FullPrescribingInformation.pdf" **to** "http://www.mallinckrodt.com/WorkArea/DownloadAsset.aspx?id=2147483728", "http://www.kadian.com/NR/rdonlyres/7503AA98-0505-4499-BB8F-0AF444188767/0/KadianPIallstrengthsJuly2012.pdf" **to** "http://kadian.com/NR/rdonlyres/E24358B1-072D-46B6-B3E2-619A6D6414BA/0/KadianPI_424.pdf", "http://www.nucynta.com/sites/default/files/pdf/nucyntaer-pi.pdf#zoom=100" **to** "http://www.nucynta.com/_assets/pdf/nucyntaer-pi.pdf", "http://www.endo.com/File%20Library/Products/Prescribing%20Information/OpanaER_Biconcave__prescribing_information-html.html" **to** "http://www.endo.com/File%20Library/Products/Prescribing%20Information/O

	panaER_prescribing_information_newformulation.html", **and** "http://www.purduepharma.com/pressroom/news/oxycontinpi.pdf" **to** "http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o" **under References**. 8. **Removed** "http://labeling.pfizer.com/ShowLabeling.aspx?id=876" **from References** (product no longer available). 9. **Added** "http://labeling.pfizer.com/showlabeling.aspx?id=694", "http://app.purduepharma.com/xmlpublishing/pi.aspx?id=h", "http://app.purduepharma.com/xmlpublishing/pi.aspx?id=ms", **and** "http://www.zohydroer.com/downloads/ZOHYDROERFullPrescribingInformation.pdf" **under References.**
2/11/2014	1. **Adapted policy to new format.** 2. **Added** "Exalgo® (hydromorphone)" **to Applicable Drugs**. 3. **Removed** "Avinza® (morphine), Opana® ER (oxymorphone), and OxyContin® (oxycodone)" **from Applicable Drugs list**. 4. **Added GPI Codes**. 5. **Changed Prior Authorization Criteria from**: "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" **to:** "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". 6. **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**. 7. **Updated references** to include Medi-Span and package inserts.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.