



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/17
LAST REVIEW DATE: 9/20/18
LAST CRITERIA REVISION DATE: 9/20/18
ARCHIVE DATE:

EXALGO® (hydromorphone hydrochloride) extended-release oral tablet HYDROMORPHONE HYDROCHLORIDE extended-release oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

**EXALGO® (hydromorphone hydrochloride) extended-release oral tablet
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Criteria:

- **Criteria for initial therapy:** Exalgo and Hydromorphone Hydrochloride ER is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual is 18 years of age or older
 2. A confirmed diagnosis of **ONE** of the following:
 - cancer related pain
 - pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options like **Short Acting Narcotics, non-opioid therapy** are ineffective, not tolerated, or inadequate
 3. Failure or clinically significant adverse effects from:
 - Morphine Extended Release
 - Embeda ER capsule
 - Nucynta ER tablet
 - Oxycodone ER tablet
 - Fentanyl transdermal
 4. Coordination of care will be performed between different prescribers for **ALL** controlled substances
 5. **For non-cancer pain:** For **morphine equivalent dosing (MED) greater than 180mg/day:**
 - A dosing schedule to bring individual to a lower dosage of MED less than 180mg/day (titration schedule required)
 6. **For non-cancer pain:** A **treatment plan**, including:
 - Pain intensity (scales or ratings)
 - Functional status (physical and psychosocial)
 - Patient's goal of therapy (level of pain acceptable and/or functional status)
 - Current non-pharmacological treatment
 7. **For non-cancer pain:** Physician-patient **pain management contract** must be provided
 8. **For non-cancer pain:** Documentation must be included for **random urine or blood tests** twice a year
 9. **For non-cancer pain:** Documentation of **PDMP reviewed** by the prescriber every time a prescription for controlled substance is provided
 10. **For non-cancer pain:** **One pharmacy (and another 24-hour closest pharmacy)** must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan*)
 11. **For non-cancer pain:** Individual has been evaluated and must **not** have an active addiction to illicit substances or prescription drugs or a drug seeking behavior

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12. There is **NO** concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc. **OR** treatment plan to taper use and coordinate care
13. There are **NO** contraindications.
- Contraindications include:
 - Opioid non-tolerant patients
 - Significant respiratory depression
 - Acute or severe bronchial asthma
 - Known or suspected gastrointestinal obstruction, including paralytic ileus
 - Individuals who have had surgical procedures and/or underlying diseases resulting in narrowing of the gastrointestinal tract, or have “blind loops” of the gastrointestinal tract or gastrointestinal obstruction, for example: esophageal motility disorders, small bowel inflammatory disease, “short gut” syndrome due to adhesions or decreased transit time, past history of peritonitis, cystic fibrosis, chronic intestinal pseudo-obstruction, or Meckel’s diverticulum
 - Known hypersensitivity to any components including hydromorphone hydrochloride and sulfites

Initial approval duration:

- Exalgo and Hydromorphone Hydrochloride ER will be approved at the requested dosage for 6 months for pain not related to cancer
- Exalgo and Hydromorphone Hydrochloride ER will be approved at the requested dosage for 12 months for pain related to cancer
- For non-cancer pain, one pharmacy (and another 24-hour closest pharmacy) must be selected for all the controlled substances prescription services (limitation may vary by specific member’s benefit plan*)

- **Criteria for continuation of coverage (renewal request):** Exalgo and Hydromorphone Hydrochloride ER is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Individual’s pain is controlled with these products
 2. Continued coordination of care between different prescribers for **ALL** controlled substances
 3. The condition has not progressed or worsened while on therapy and no development of severe side effects like:
 - Apnea, dyspnea, epistaxis, hemoptysis, hyperventilation, hypoxia, upper respiratory infection etc.
 - Confusion/speech disturbance
 - Dehydration
 - Atrial fibrillation/arrhythmia/chest pain
 - Ascites
 4. **For non-cancer pain:** A **treatment plan**, including:
 - Pain intensity (scales or ratings)



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- Functional status (physical and psychosocial)
 - Patient's goal of therapy (level of pain acceptable and/or functional status)
 - Current non-pharmacological treatment
5. **For non-cancer pain:** Physician-patient pain management contract must be provided
 6. **For non-cancer pain:** Documentation must be included for random urine or blood tests twice a year
 7. **For non-cancer pain:** Documentation of PDMP reviewed by the prescriber every time a prescription for controlled substance is provided
 8. **For non-cancer pain:** One pharmacy (and another 24-hour closest pharmacy) must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan*)
 9. **For non-cancer pain:** Individual has been evaluated and must **not** have an active addiction to illicit substances or prescription drugs or a drug seeking behavior
 10. There is **NO** concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc. OR treatment plan to taper use and coordinate care

Renewal duration:

- Exalgo and Hydromorphone Hydrochloride ER will be approved at the requested dosage for 6 months for pain not related to cancer
- Exalgo and Hydromorphone Hydrochloride ER will be approved at the requested dosage for 12 months for pain related to cancer
- For non-cancer pain, one pharmacy (and another 24-hour closest pharmacy) must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan*)

*For Qualified Health Plans (**QHP**) for Individuals/Families and Small Groups:

"**Narcotics Designated Network Program**" is a program that requires certain members taking narcotic medications to obtain prescriptions for all covered narcotic medications from one designated eligible physician or other provider and to obtain all covered narcotic medications from one network pharmacy designated by BCBSAZ and/or the PBM.

- **Patients should be tapered off or lower the dosage if any of the following apply: See "Definitions" section for Tapering guidelines**
 - The patient has committed serious or repeated drug seeking behavior
 - The patient makes no progress toward therapeutic goals
- **For all patients receiving more than 200 mg morphine or equivalent per 24 hours: See "Definitions" section for Tapering guidelines**
 - Taper patient to a lower dosage
 - Provide a Naloxone prescription to avoid side effects



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- Initiate/augment non-opioid treatments
- Provide BH/Case management support to help with the taper

Description:

Exalgo (hydromorphone) and Hydromorphone hydrochloride ER are indicated for the 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 (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Exalgo (hydromorphone) Hydromorphone hydrochloride ER are not indicated as an as-needed (prn) analgesic.

Hydromorphone, a semi-synthetic morphine derivative, is an agonist of mu-opioid receptors. The precise mechanism of action of opioid analgesics is not known but the effects are thought to be mediated through opioid-specific receptors located predominantly in the central nervous system (CNS).

Pain is a subjective episode described as an unpleasant, multi-dimensional, sensory, and emotional experience associated with actual or potential tissue damage or described in relation to such damage. The perception of pain is further influenced by physical, psychological, social, cultural, and hereditary factors. Persistent pain will often require treatment with regularly scheduled analgesics and supplemental analgesics for breakthrough periods. Chronic pain can be defined as any pain that persists beyond the anticipated time of normal tissue healing, which is generally assumed to be three months. Chronic pain may be caused by numerous medical conditions and syndromes with widely divergent pathophysiology.

Opioid analgesic medications relieve a wide variety of pain syndromes and are generally accepted for the treatment of severe acute pain and chronic pain related to active cancer. In contrast, the use of chronic opioid therapy to treat other types of chronic pain not associated with malignancy remains controversial. There is a large amount of clinical experience with opioids for the treatment numerous pain syndromes, yet there are limited data on the safety and efficacy of long-term opioid therapy for chronic non-cancer pain.

There are many agents available with brand and generic options for the treatment of pain. Several agents are also available as both immediate- (or short-) acting and long-acting formulations. There are clinically meaningful differences in potency, time to onset, elimination and duration of action among the various compounds.

Long-acting opioids are more convenient than short-acting opioids for the treatment of chronic pain conditions, although there is no reliable evidence of their superiority. There is no reliable comparative evidence demonstrating that one long-acting opioid is more effective than another opioid analgesic, including immediate-acting or other long-acting formulations.

Specific central nervous system (CNS) opiate receptors and endogenous compounds with morphine-like activity have been identified throughout the brain and spinal cord and are likely to play a role in the expression and perception of pain. Opioid receptors have also been identified within the peripheral nervous system (PNS). The primary site of therapeutic action of opioids is within the CNS. Opioid agonists are thought to reduce pain by

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acting primarily through interaction with opioid mu-receptors located in the brain, spinal cord, and smooth muscle. Opioid agonists produce respiratory depression by direct action on the brain stem respiratory center.

All opioids have the potential to cause respiratory depression, abuse and physical dependence. None have been proven to be safer than another. One method employed by manufacturers to mitigate abuse of opioids has been formulating products that are difficult to extract the main opioid ingredient from the original form. Providers should individualize treatment of pain in every case, using non-opioid analgesics, opioids on an as needed basis, combination products, and when appropriate chronic opioid therapy in a progressive comprehensive plan of pain management.

The World Health Organization's (WHO) guidelines for cancer pain management recommends a three-stepped approach with consideration for the type of pain and response to therapy. Initial therapy includes non-opioid analgesics such as non-steroidal anti-inflammatory drugs (NSAIDs). For mild to moderate pain, oral combinations of acetaminophen and NSAIDs with opioids are recommended. For moderate to severe pain, opioid analgesics are recommended. Titration of dose and frequency is individualized to the patient's response and development of adverse effects. For patients with inadequate pain relief and intolerable opioid-related toxicity/adverse effects, a switch to an alternative opioid may be an option for obtaining symptomatic relief.

The National Comprehensive Cancer Network (NCCN) 2015 Clinical Practice Guideline in Oncology: Adult Cancer Pain outlines numerous steps in managing opioid medications in cancer pain that can be adapted for non-cancer pain management. Examples of some of the recommendations include: use short-acting opioid medications for titration, for persistent pain initiate regular schedule of opioid with a rescue dose as needed, calculate opioid dose increase based on the total 24-hour dose (around the clock/scheduled and as needed doses), when possible, use the same short-acting and long-acting opioid formulation, and simplify regimen for improved adherence.

In theory, opioids have no maximum or ceiling dose; however recent guidelines suggest close evaluation of individuals using large doses of opioid medications to identify unique opioid related adverse effects.

Definitions:

CDC Recommendations for Opioid Prescribing for Chronic Pain:

A. Determining when to initiate or continue opioids for chronic pain

1. Opioids are not first-line or routine therapy for chronic pain
2. Establish and measure goals for pain and function
3. Discuss benefits and risks and availability of non-opioid therapies with patient

B. Opioid selection, dosage, duration, follow-up, and discontinuation

1. Use immediate-release opioids when starting
2. Start low and go slow-Use caution at any dose and avoid increasing to high dosages
3. When opioids are needed for acute pain, prescribe no more than needed
 - Do NOT prescribe ER/LA opioids for acute pain

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4. Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if opioids cause harm or are not helping

C. Assessing risk and addressing harms of opioid use

1. Evaluate risk factors for opioid-related harms
2. Check CSPMP for high dosages and prescriptions from other providers at the beginning of the treatment and at least quarterly while on the opioid treatment
3. Use urine drug testing to identify prescribed substances and undisclosed use
4. Avoid concurrent benzodiazepine and opioid prescribing
5. Arrange treatment for opioid use disorder if needed

Prescriber Education:

- Guidelines for Prescribing Opioids for Chronic Pain
https://www.cdc.gov/drugoverdose/pdf/TurnTheTide_PocketGuide-a.pdf
http://www.agencymeddirectors.wa.gov/Files/FY16-288SummaryAMDGOpioidGuideline_FINAL.pdf
https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf
- Checklist for prescribing opioids for chronic pain
https://www.cdc.gov/drugoverdose/pdf/PDO_Checklist-a.pdf
- Tapering Opioids for Chronic Pain
https://www.cdc.gov/drugoverdose/pdf/Clinical_Pocket_Guide_Tapering-a.pdf
- Non-Opioid Treatments
https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf
- Assessing Benefits and Harms of Opioid
https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf
- Calculating Total Daily Dose of Opioids for Safer Dosage
https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf
- Checking Controlled Substances Prescription Monitoring Program (CSPMP)
<https://arizona.pmpaware.net/login>
<https://pharmacympm.az.gov/>
- Educational Webinar Series for Prescribers
<https://www.cdc.gov/drugoverdose/pdf/COCA-webinar-series-allslides-a.pdf>
<https://www.cdc.gov/drugoverdose/prescribing/trainings.html>
<http://www.coperems.org/>
- CDC Guideline for Prescribing Opioids for Chronic Pain
<https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html>

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- Washington State Opioid Taper Plan Calculator
www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf
- Tapering Long-Term Opioid Therapy in Chronic Non-cancer Pain
[www.mayoclinicproceedings.org/article/S0025-6196\(15\)00303-1/fulltext](http://www.mayoclinicproceedings.org/article/S0025-6196(15)00303-1/fulltext)
- UpToDate
https://www.uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-treatment-of-chronic-non-cancer-pain?source=search_result&search=non-cancer%20pain&selectedTitle=1~150

Opioid Risk Assessment Tool:

Score each that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16-45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disorders		
ADD, OCD, Bipolar, Schizophrenia	2	2
Depression	1	1
Total score		
Assessment of risk		
Low risk for abuse	< 3	
Moderate risk for abuse	4-7	
High risk for abuse	> 8	
Definitions of risk		
Low = unlikely to abuse		
Moderate = as likely will as will not abuse		
High = likely to abuse		

Resources:

Exalgo. Package Insert. Revised by manufacturer 01/2017. Accessed 05/02/17.



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Hydromorphone HCl ER. Package insert. Revised by manufacturer 09/2016. Accessed 05/08/17.
National Comprehensive Cancer Network Clinical Practice Guideline in Oncology: Adult Cancer Pain version 2.2015

Institute for Clinical Systems Improvement Health Care Guideline: Assessment and management of chronic pain. 5th edition, November 2011

Opioid Treatment Guidelines: Clinical Guidelines for the use of chronic opioid therapy in chronic non-cancer pain. J of Pain 2009; 10(2):113-130

Practice guidelines for chronic pain management: An updated report by the American Society of Anesthesiologists Task Force on chronic pain management and the American Society of Regional Anesthesia and Pain medicine. Anesthesiology 2010; 112(4): 1-24

Cancer pain relief: with a guide to opioid availability. World Health Organization 1996
Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.



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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com. Call 866-325-1794 to check the status of a request. All requested data must be provided. Incomplete forms or forms without the chart notes will be returned. Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Opioid Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:
Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	
Dispensing Pharmacy Information			
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:	
Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:
<input type="checkbox"/> Check if requesting brand only <input type="checkbox"/> Check if requesting generic			
<input type="checkbox"/> Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)			
Turn-Around Time For Review			
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____ <input type="checkbox"/> Exigent (requires prescriber to include a written statement)			
Clinical Information			
1. Select all applicable diagnoses below. <input type="checkbox"/> Confirmed diagnosis of <u>pain severe</u> enough that is not controlled by the current dosage <input type="checkbox"/> Confirmed diagnosis of <u>Migraines</u> <input type="checkbox"/> Confirmed diagnosis of <u>Neuropathic Pain</u> <input type="checkbox"/> Confirmed diagnosis of <u>Osteoarthritis</u> <input type="checkbox"/> Confirmed diagnosis of <u>Fibromyalgia</u> <input type="checkbox"/> Other diagnosis: _____ ICD-10 Code(s): _____			
2. What is the quantity requested per day? _____			
3. What is the reason for <u>exceeding</u> the plan limitations? Please specify below (if applicable). _____			
4. For Migraines: Check all applicable <u>non-opioid</u> therapies failed, intolerated, or contraindicated. PREVENTATIVE TREATMENTS <input type="checkbox"/> Anticonvulsants (Topiramate) <input type="checkbox"/> Beta-Blockers (Propranolol, Atenolol) <input type="checkbox"/> TCAs (Amitriptyline, Imipramine) <input type="checkbox"/> Calcium Channel Blockers (Amlodipine, Verapamil) <input type="checkbox"/> Non pharmacological treatments (Cognitive behavioral therapy, Relaxation, Biofeedback, Exercise therapy) ACUTE TREATMENTS <input type="checkbox"/> Aspirin, Acetaminophen, NSAIDS (Naproxen, Ibuprofen, Meloxicam, Diclofenac) may be combined with caffeine <input type="checkbox"/> Anti-nausea medication (Ondansetron, Promethazine) <input type="checkbox"/> Triptans - migraine-specific (Rizatriptan, Sumatriptan)			
5. For Neuropathic Pain: Check all applicable <u>non-opioid</u> therapies failed, intolerated, or contraindicated. <input type="checkbox"/> TCAs (Amitriptyline, Imipramine) <input type="checkbox"/> SNRIs (Duloxetine, Venlafaxine) <input type="checkbox"/> Gabapentin/Lyrica <input type="checkbox"/> Topical Aspercreme 4% cream or Patches <input type="checkbox"/> Non pharmacological treatments (Exercise, Weight loss, patient education)			

Opioid Prior Authorization Request Form

6. For Osteoarthritis: Check all applicable non-opioid therapies failed, intolerated, or contraindicated.

FIRST LINE

- Acetaminophen
- Oral NSAIDs (Naproxen, Ibuprofen, Meloxicam, Diclofenac)
- Topical NSAIDs (Diclofenac Gel)

SECOND LINE

- Intra-articular hyaluronic acid (OA of the knee only)
- Capsaicin

7. For Fibromyalgia: Check all applicable non-opioid therapies failed, intolerated, or contraindicated.

- Duloxetine
- Lyrica
- Gabapentin
- TCAs (Amitriptyline, Imipramine)
- Non pharmacological treatments (Low impact aerobic exercise such as brisk walking, swimming, water aerobics or bicycling. Cognitive behavioral therapy, biofeedback, interdisciplinary rehabilitation)

8. Yes No A treatment plan must be submitted with this request form that includes ALL of the following:

- Pain intensity (scales or ratings)
- Functional status (physical and psychosocial)
- Patient's goal of therapy (level of pain acceptable and/or functional status)
- Current non-pharmacological treatment

9. Yes No A physician-patient pain management contract must be submitted with this request form.

10. Yes No Individual must not be actively using illicit substances or NOT have a drug seeking behavior.

11. Yes No Results from random urine or blood test twice a year must be submitted with this request form.

12. Yes No Has the state's Prescription Drug Monitoring Program (PDMP) been reviewed for this individual every time a prescription for controlled substance is provided?

13. What other controlled substances is the patient currently receiving? Please specify below.

14. One pharmacy (plus one closest 24 hour pharmacy) must be selected for all the controlled substances prescription services. Please specify:

15. Yes No There is NO concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc.

16. Yes No There is absence of ALL contraindications.

17. What medication(s) has the individual tried and failed for this diagnosis? Please specify below.

Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

18. Are there any supporting labs or test results? Please specify below.

Date	Test	Value

Opioid Prior Authorization Request Form

19. Is there any additional information the prescribing provider feels is important to this review? Please specify below.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature:

Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.