TARGET DRUG REVIEW
Hydromorphone Hydrochloride Extended-Release
(*Palladone*)

Patient's Name: _____ **Patient's Initials:** _____

Patient's ID #: _____ **Date:** _____

Birth Date: _____ **Age**: _____ **Sex:** _____ **Weight:** _____ (kg or lbs)

Provider: _____ **SCr:** _____ (mg/dL)
CrCl: _____ (mL/min)

Justification:

FDA-Approved Use:

__ Treatment of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with high-potency opioid for an extended period of time (weeks to months) or longer.

Non-FDA-Approved Uses:

__ Acute pain
__ Chronic pain
__ Other type: _____

If the drug is being used for a non-FDA-approved use, is the patient enrolled in a clinical trial? ❑ Yes ❑ No

Process Indicators:

__ Signs and symptoms of above medical problem described in the medical record
__ Indication documented with:
  __ Signs and symptoms: _____
  __ Patient was previously receiving continuous opioid therapy
  __ Patient was tolerant to previous opioid therapy*

* = Definition of tolerance to previous opioid therapy are those patients requiring at least 8 mg oral hydromorphone/day or an equianalgesic dose of another opioid for a week or longer.

Examples of Opioid Tolerance	
Opioid	**≥ mg/day**
Hydromorphone	8
Morphine, oral	60
Oxycodone	30

Previous opioid therapy:

Drug	**Dose (mg/day)**	**Hydromorphone equivalence* (mg/day)**	**Comments**

*mg/day multiplied by the conversion factor from the following table:

Prior Opioid	Oral	Parenteral
Codeine	0.04	--
Hydrocodone	0.22	--
Hydromorphone	1	5
Levorphanol	1.88	3.75
Meperidine	0.02	0.1
Methadone	0.38	0.75
Morphine	0.12	0.75
Oxycodone	0.25	--

Conversion for transdermal fentanyl: 50 mcg/hour transdermal fentanyl is equivalent to *Palladone* 12 mg

Contraindications to Use:

Contraindications	Absent	Present
Allergic or hypersensitivity reaction to hydromorphone hydrochloride		
No history of allergic reaction to ammonio methacrylate copolymer type B, ethylcellulose, stearyl alcohol, gelatin, synthetic black iron oxide, titanium dioxide, miscellaneous dyes		
As-needed administration (PRN)		
Situations of significant respiratory depression, especially in unmonitored settings where there is a lack of resuscitative equipment		
Acute or severe bronchial asthma		
Documented or suspected of having paralytic ileus		

Precautions/Warnings:

Precautions/Warnings	Absent	Present
Abuse		
Addiction		
Adrenocortical insufficiency (eg, Addison disease)		
Alcohol abuse, history		
Biliary tract disease (eg, acute pancreatitis)		
CNS depression		
Coma		
Debilitation		
Diversion		
Drug abuse, history		
Head injury		
Hepatic function impairment, severe		
Hypotension		
Hypothyroidism		
Kyphoscoliosis associated with respiratory depression		
Myxedema		
Prostatic hypertrophy		
Renal function impairment, severe		
Respiratory depression		
Risk of respiratory depression: significant chronic obstructive pulmonary disease, cor pulmonale, substantial decrease in respiratory reserve, hypoxia, or hypercapnia		
Seizures, history		
Toxic psychosis		
Urethral stricture		

__ Pregnancy (Category C)
__ Labor and delivery (initiation not recommended during this time period or immediate postpartum; therapy should be continued to avoid withdrawal but neonate needs to be monitored for withdrawal symptoms)
__ Nursing woman (low concentration; nursing not advised)

Concurrent use with other analgesic medications (supplemental or rescue):

Drug	Date Started	Date Stopped	Route of Administration	Dosing Range Used	Comments
Acetaminophen					
Aspirin					
NSAIDs					Specify which drug is being used.
Fentanyl transmucosal					
Fentanyl transdermal					
PRN opioid – immediate-release					Specify which drug is being used.

Adverse Effects: (eg, asthenia, constipation, headache, infection, nausea, pruritus, vomiting, somnolence)
__ No ADR __ ADR, appropriate action taken __ ADR, appropriate action NOT taken
__ Problem resolved __ Problem NOT resolved

If an adverse effect occurred, note the date, location of description in chart (eg, progress notes), type of reaction, and action taken (drug discontinued, other drugs discontinued, dosage changed, etc.).

Drug Interactions: (additional CNS depression – other opioid analgesics, general anesthetics, phenothiazine, tricyclic antidepressants, alcohol, barbiturates, sedatives, hypnotics, centrally acting antiemetics, benzodiazepines, and other CNS depressant medications; additional respiratory depression – muscle relaxants; reduction in analgesic effect or precipitate of withdrawal symptoms – agonist/antagonist analgesics (eg, pentazocine, nalbuphine, butorphanol; monoamine oxidase inhibitors [MAOIs] – recommended that they be discontinued at least 2 weeks prior to initiation of therapy).

__ No DI __ DI, appropriate action taken __ DI, appropriate action NOT taken
__ Problem resolved __ Problem NOT resolved

Dosing:

__ Adult patient: Starting dose depends on the dose of the previous opioid analgesic

__ Pediatric patient (Note: safety and effectiveness have not been established in patients younger than 18 years of age)

__ Tablets are NOT broken, chewed, dissolved, or crushed prior to administration

Outcome Criteria:

__ Improvement in the signs and symptoms of indicated medical problem
__ Therapy discontinued because of an adverse reaction
__ Therapy discontinued because of lack of efficacy
__ Patient left facilities against medical advice
__ Patient failed to return for follow-up visits
__ Other:

REFERENCES:

1. Angst MS, Drover DR, Lotsch J, et al. Pharmacodynamics of orally administered sustained-release hydromorphone in humans. *Anesthesiology.* 2001;94:63-73.

2. *Palladone* [package insert]. Standford, CT: Purdue Pharma L.P.; September 2004.

3. Palangio M, Northfelt DW, Portenoy RK, et al. Dose conversion and titration with a novel, once-daily, *OROS* osmotic technology, extended-release hydromorphone formulation in the treatment of chronic malignant or nonmalignant pain. *J Pain Symptom Manage.* 2002;23:355-368.