



Prior Authorization Approval Criteria

Exalgo (hydromorphone)

Generic name:	hydromorphone
Brand name:	Exalgo
Medication class:	Opioid analgesic
FDA-approved uses:	Management of moderate to severe pain in opioid tolerant patients requiring continuous, around the clock opioid analgesia for an extended period of time.
Available dosage forms:	8mg, 12 mg or 16 mg tablets
Usual dose:	The dose range in clinical trials is 8 mg-64 mg administered once every 24 hours.

Previous Opioid	Conversion Ratios to EXALGO* Approximate Equivalent Oral Dose	Oral Conversion Ratio _a
Hydromorphone	2 mg	1
Codeine	200 mg	0.06
Hydrocodone	30 mg	0.4
Methadone _b	20 mg	0.6
Morphine	60 mg	0.2
Oxycodone	30 mg	0.4
Oxymorphone	20 mg	0.6

Select opioid, sum the total daily dose, and then multiply the dose by the conversion ratio to calculate the approximate oral hydromorphone equivalent.

^a Ratio for conversion of oral opioid dose to approximate hydromorphone equivalent dose.

^b **It is extremely important to monitor all patients closely when converting from methadone to other opioid agonists.** The ratio between methadone and other opioid agonists may vary widely as a function of previous dose exposure. Methadone has a long half-life and tends to accumulate in the plasma.

* **The conversion ratios and approximate equivalent doses in this conversion table are only to be used for the conversion from current opioid therapy to EXALGO.**

Conversion from Transdermal Fentanyl to EXALGO

Eighteen hours following the removal of the transdermal fentanyl patch, EXALGO treatment can be initiated. For each 25 mcg/hr fentanyl transdermal dose the equianalgesic dose of EXALGO is 12 mg every 24 hours. An appropriate starting dose of EXALGO is 50% of the calculated total daily dose every 24 hours.

Duration of therapy: Indefinite

Approximate cost: (based on AWP 2010)	<u>Strength</u>	<u>Cost per pill</u>
	8 mg	\$10.00
	12 mg	\$15.00
	16 mg	\$20.00

Criteria for use *(bullet points below are all inclusive unless otherwise noted):*

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Only approved for patients who are already receiving and who are tolerant to opioid therapy.
- Patients considered opioid-tolerant are those who are taking at least 60 mg morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for a week or longer.
- Must be 18 years of age or older.
- Must try and fail an adequate dose of a formulary long-acting narcotic such as morphine sulfate, methadone, or fentanyl patches.

Caution:

- Caution in patients with hepatic or renal impairment. The lowest possible dose should be used.

Contraindications:

- Impaired pulmonary function.
- Paralytic ileus.
- Narrowed or obstructed gastrointestinal tract.
- Contraindicated in opioid non-tolerant patients.
- Patients with known intolerance or hypersensitivity to any of its components or the drug hydromorphone hydrochloride and sulfites.

Not approved if:

- Patient has any contraindications to the use of hydromorphone.
- Patient does not meet above requirements.
- Patient has known past or current substance abuse potential.
- Patient is on Suboxone or Subutex.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 09/08/10