Drug Use Research & Management Program
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Month/Year of Review: November 2014 **Date of Last Review:** August 2013
PDL Classes: Nonsteroidal Anti-inflammatory Drugs (NSAIDS) **Source Document:** DERP

Current Status of PDL Class:

- Preferred Agents: DICLOFENAC POTASSIUM, DICLOFENAC SODIUM DR, ETODOLAC TABLET, FLURBIPROFEN, IBUPROFEN CAPSULE/DROPS/ORAL SUSP/CHEWABLE/TABLET, INDOMETHASONE CAPSULE, KETOPROFEN, MELOXICAM, NABUMETONE, NAPROXEN TABLET, NAPROXEN DR, NAPROXEN SODIUM, OXAPROZIN, SALSALATE, SULINDAC
- Non-Preferred Agents: CELECOXIB (CELEBREX®), DICLOFENAC TAB ER 24H, DIFLUNISAL, ETODOLAC CAPSULE, ETODOLAC TABLET ER 24H, FENOPROFEN, INDOMETHASONE ORAL SUSPENSION/CAPSULE ER, KETOPROFEN CAPSULE 24H, KETOROLAC TALET, KETOROLAC NASAL SPRAY (SPRIX®), MECLOFENAMATE SODIUM, MEFENAMIC ACID, NAPROXEN CAPSULE, PIROXICAM ,TOLMETIN SODIUM, NAPROXEN AND ESOMEPRAZOLE (VIMOVO®)

Previous Conclusions and Recommendation:

- For pain relief, no significant short-term (< 6 months) differences were found among oral NSAIDs.
- For serious harms, celecoxib did not appear to be associated with higher risk of cardiovascular (CV) events and is gastroprotective in the short term compared with nonselective NSAIDs.
- Findings vary by subgroup, depending on age, recent history of gastrointestinal bleeding, and concomitant use of antiulcer medication.
- Nonselective NSAIDs were associated with similar increased risks of serious GI events, and all but naproxen were associated with similar increased risk of serious CV events, but eh partially selective NSAID nabumetone was gastroprotective compared with nonselective NSAIDs.
- A meta-analysis of randomized controlled trials showed diclofenac to be associated with an increased incidence of major vascular events (driven by coronary events) and death due to vascular causes, similar to those seen with selective COX-2 inhibitors, such as celecoxib. Naproxen was shown to confer less cardiovascular (CV) risk.
- A meta-analyses of observational data showed diclofenac to have a higher risk of acute myocardial infarction (MI) than other commonly used NSAIDS.2
- Gastrointestinal (GI) risks were similar for diclofenac compared to other NSAIDS.
- Overall, there is limited evidence on safety data associated with diclofenac therapy and the inherent risks associated with all NSAIDs.

PA Criteria: Prior authorization is in place to ensure that non-preferred NSAIDs are used for above the line conditions and to restrict ketorolac to short-term use (5 days every 60 days) per the FDA black boxed warning (Appendix 1).

Methods:

The DERP Scan was used to identify any new comparative research that has emerged since the last P&T review.[1]

Conclusions and Recommendations:

- No further review or research needed.
- Evaluate comparative costs in executive session.

References:

1. Peterson, Kim. Drug Effectiveness Review Project: Drug Class Review Nonsteroidal Anti-inflammatory Drugs (NSAIDs). Preliminary Scan Report #2, May 2014.

Appendix 1: PA Criteria

Analgesics, Non-Steroidal Anti-Inflammatory Drugs

Goal(s):

- The purpose of this prior authorization policy is to ensure that non-preferred NSAIDs are used for an above the line condition and restrict ketorolac to short-term use (5 days every 60 days) per the FDA black boxed warning.

WARNING - Ketorolac is indicated for the short-term (up to 5 days) management of moderately severe acute pain that requires analgesia at the opioid level. It is not indicated for minor or chronic painful conditions. Ketorolac is a potent NSAID analgesic, and its administration carries many risks. The resulting NSAID-related adverse events can be serious in certain patients for whom ketorolac is indicated, especially when the drug is used inappropriately. Increasing the dose beyond the label recommendations will not provide better efficacy but will result in increasing the risk of developing serious adverse events.

Length of Authorization: Up to 12 months

Requires PA:

- Non-preferred NSAIDs
- Ketorolac: Maximum of one claim per 60 days. That claim can be a maximum of 20tablets/5 days, i.e. there is a 5 day maximum per 60 days.

Preferred Alternatives: Preferred alternatives listed at: http://www.orpdl.org/

Approval Criteria		
1. What is the diagnosis?	Record ICD9 code	
2. Is the diagnosis covered by the Oregon Health Plan? All indications need to be evaluated as to whether they are above the line or below the line.	**Yes:** Go to #3	**No**: Pass to RPH; Deny, (Not covered by the OPH)
3. Is this a continuation of current therapy (i.e. filled prescription within prior 90 days)? Verify via pharmacy claims.	**Yes:** Document prior therapy in PA record. Go to #4	**No**: Go to #5
4. Is request for ketorolac greater than a 5 day supply within 60 days (200mg total over 5 days for tablets, 630mg total over 5 days for the nasal spray)?	**Yes:** Pass to RPH; Deny, (Medical Appropriateness). Review FDA warnings	**No:** Go to #5
5. Will the prescriber consider a change to a preferred product? Message:	**Yes:** Inform provider of covered alternatives in class.	**No:** Approve for 1 year or length of prescription, whichever is less.

• Preferred products do not require PA. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee.		

P&T/DUR Action: 2/23/12 (TW). 9/24/09 (DO/KK), 2/23/06
Revision(s): 5/14/12, 1/1/10
Initiated: ?