Step Therapy Edit Criteria Proposal

Drug/Drug Class:	**NSAID Step Therapy Edit**
Date:	**August 12, 2010**
Prepared for:	
Prepared by:	MO HealthNet

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose:	Reduce the average cost per prescription claim for Non-Steroidal Anti-inflammatory Drugs (NSAIDs) by implementing a preferred drug product.
Why was this Issue Selected:	The MO HealthNet Pharmacy Program began the clinical edit process in December 2002 by implementing the edit on Cox II inhibitors. Unforeseen consequences of this edit were a shift to the more expensive non-selective NSAID's such as meloxicam and naproxen. Evidence-based reviews do not support a clinical benefit in using these non-selective agents over others in the subclass. To assist providers with claims processing, and to reduce program costs, Ibuprofen will be the reference product, and therefore have no clinical edits imposed.
Program Specific Information:	During the twelve-month calendar period of June 2002 to May 2003, 332,565 claims were paid for NSAID therapy at a cost of $7,709,369. This dollar amount represents approximately 0.8% of the total prescription drug benefit spend over that same calendar period. Potential cost savings using Ibuprofen as the reference product is $2.5 million per year.
Setting & Population:	All patients prescribed NSAIDs other than the reference drug.
Type of Criteria:	☐ **Increased risk of ADE** ☒ **Non-Preferred Agent** ☒ **Appropriate Indications** ☐
Data Sources:	☒ **Only administrative databases** ☐ **Databases + Prescriber-supplied**

Approval Criteria

Reference Drug Products: Piroxicam, Ibuprofen, and Naproxen (Sodium)

- Patient currently prescribed a non-reference NSAID product that demonstrates therapy compliance
- Patient has documented adverse drug event to the reference NSAID products
- Patient has documented therapeutic failure to the reference NSAID products
- Patient currently prescribed a non-reference NSAID product with history of an adequate trial period with reference NSAID products
- Claims for Flector require diagnosis of acute pain due to minor strains, sprains, or contusions
    - Approved for short-term acute therapy (1 box of 30 patches)
- Claims approved for Ketorolac are limited to short-term acute therapy for a maximum of 40mg per day for a maximum of 5 days.

Denial Criteria

- Lack of compliance to non-reference NSAID therapy
- Lack of therapeutic failure or trial period of reference NSAID products
- Lack of documented adverse drug reaction to reference NSAID products.

Reference Drug/Drugs with No Clinical Edit Imposed

- Ibuprofen
- Naproxen (Naprosyn(Anaprox®)
- Piroxicam (Feldene®)

Drugs, Which Will be Affected by the Step Therapy Edit

- Diclofenac (Voltaren®, Cataflam®)
- Diclofenac with Misoprostol (Arthrotec®)
- Diflunisal (Dolobid®)
- Etodolac (Lodine®)
- Fenoprofen (Nalfon®)
- Flurbiprofen (Ansaid®)
- Indomethacin (Indocin®)
- Ketoprofen (Orudis®)
- Ketorolac (Toradol®)
- Meclofenamate
- Mefenamic Acid (Ponstel®)
- Meloxicam (Mobic®)
- Nabumetone (Relafen®)
- Oxaprozin (Daypro®)
- Sulindac (Clinoril®)
- Tolmetin (Tolectin®)
- Naproxen with Lansoprazole (NapraPac®)
- ***Diclofenac Epolamine (Flector®)***

Required Documentation

Appropriate Diagnosis: ☐ Progress notes: ☐
MedWatch form: ☐

Disposition of Edit

- **Denial:** Exception 681 “Step Therapy”

References

1. Facts and Comparisons, p.835-48a. 2003.
2. USPDI, Micromedex, 2003.
3. “Evidence-based Medical Analysis: NSAID’s”, Cassica Schlicktmann, Pharm D. Candidate, Drake University, February 2003.