Clinical Edit Criteria Proposal

Drug/Drug Class:	**Butorphanol Clinical Edit**
Date:	**June 29, 2011**
Prepared for:	
Prepared by:	**MO HealthNet**

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

Executive Summary

Purpose:

Ensure appropriate and prudent use of butorphanol within the MO HealthNet Pharmacy program.

Why was this Issue Selected:

Butorphanol is a morphine-like synthetic opioid analgesic. It is most closely structurally related to levorphanol and is available only in injectable and intranasal spray formulations. Butorphanol exhibits partial agonist and antagonist activity at the μ opioid receptor and agonist activity at the κ opioid receptor. Stimulation of these receptors on central nervous system neurons causes an intracellular inhibition of adenylate cyclase, closing of influx membrane calcium channels, and opening of membrane potassium channels. This leads to hyperpolarization of the cell memberane potential and suppression of action potential transmission of ascending pain pathways. κ-agonism can cause dysphoria at therapeutic or supertherapeutic doses. This gives butorphanol a lower potential for abuse than other opioid drugs. Butorphanol has FDA approved indications for: pain, labor pain, anesthesia maintenance in balanced anesthesia as an adjunct and premedication for procedures. It is often used in the treatment of migraines but this is not an FDA approved indication. On a mg-to-mg basis, Butorphanol is 5 to 8 times more potent as an analgesic than morphine and 30 to 50 times more potent than meperidine.

Setting & Population:

Patients 18 years of age and older

Type of Criteria:

☐ **Increased risk of ADE** ☐ **Non-Preferred Agent**

☒ **Appropriate Indications** ☐ **Other:**

Data Sources:

☐ **Only administrative databases** ☒ **Databases + Prescriber-supplied**

Program-Specific Information:	Drug	Claims	Expense
•	Butorphanol Nasal Spray	1,188	$51,547.00
•	Butorphanol Injection	50	$ 854.00
	Totals	**1,238**	**$52,401.00**

9/2009 – 8/2010

Setting & Population

- Age range: Patients 18 years of age or older
- Gender: males and females

Approval Criteria

- Appropriate diagnosis (see diagnosis table – Appendix A)
- Doses not exceeding recommended maximum doses.

Approval Diagnoses (Appendix A)

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs**	Date Range	Client Approval
Cancer	140 – 208	NA	2 years	
	NA	Antineoplastics	12 months	
Chronic nonmalignant pain (CNMP)	282-355 710-733.7	NA	1 year	
	NA	Non-opioid analgesics	90 days	
Migraine	625.4	--	1 year	
	346.0 – 346.9	5-HT1 Serotonin Receptor Agonists	1 year	

**see Appendix B for product-specific list of Inferred Drugs

Denial Criteria

- Use of more than six canisters per 30 days
  - 15ml per month
- Patients under18 years of age

Required Documentation

Laboratory results: ☐
MedWatch form: ☐
Progress notes: ☐

Disposition of Edit

- **Denial:** Edit 682 "Clinical Edit"

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2010.
2. Facts and Comparisons; 2010.
3. USPDI, Micromedex, 2010.