Clinical Edit Proposal

Drug/Drug Class:	**Suboxone® (Buprenorphine/Naloxone)/ Partial Opioid Agonist/Opioid Antagonist**
Date:	**June 14, 2011**
Prepared for:	**MO HealthNet**
Prepared by:	**ACS - Heritage Information Systems, Inc.**

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

Executive Summary

Purpose:

The purpose of this edit is to update the needed approval/denial criteria for suboxone.

Dosage Forms & Manufacturer:

- Sublingual hexagonal orange tablet containing either
  - 2 mg buprenorphine with 0.5 mg naloxone, or
  - 8 mg buprenorphine with 2 mg naloxone
- Also available as 2 mg and 8 mg sublingual tablets containing only buprenorphine (Subutex®)
- Reckitt Benckiser Pharmaceuticals, Inc.: Richmond, VA

Summary of Findings:

Buprenorphine/naloxone (Suboxone®) and buprenorphine (Subutex®) are sublingual tablets approved by the FDA for the treatment of opioid dependence. Research was gathered to assess the safety and efficacy of suboxone. When it comes to safety data there have been numerous studies that have shown an increased effect of respiratory depression leading to death from the use of suboxone with benzodiazepines. Also, the current guidelines for the use of suboxone state that in opioid dependent women who are pregnant the standard or care is methadone. The majority of data suggests that counseling helps to improve treatment outcomes while on suboxone, and thus can increase the medication's efficacy.

Status Recommendation:

☐ Prior Authorization (PA) Required ☐ Open Access
☒ Clinical Edit

Type of PA Criteria:

☐ Increased Risk of ADE ☐ Non-Preferred Agent
☒ Appropriate Indications ☐ PA Not Required

Setting & Population

Patients who have been diagnosed with Opioid Drug Dependence

Drug Interaction with Benzodiazepines

There have been many studies that have looked at the effect of the misuse of buprenorphine and concurrent use of benzodiazepines. The general thought is that the interaction between buprenorphine and benzodiazepines is pharmacodynamic in nature. This interaction can lead to increased respiratory depression and in some cases it can be fatal.[1] With there being a greater tendency for patients suffering from opioid addiction to misuse their medication, there is a high chance of the combination being fatal in this patient population. Therefore, patients who are currently receiving treatment with Suboxone should not concurrently be on benzodiazepines unless specifically required per the physician.[2]

Pregnancy

The current guidelines for the use of buprenorphine in the treatment of opioid addiction indicate that methadone is currently the standard of care in the United States for the treatment of opioid addiction in pregnant women.[2] There have been a few studies that have compared methadone and buprenorphine in opioid addicted pregnant women. The Cochrane Database recently did a review and found two RCT trials that compared the effect of methadone and buprenorphine in this patient population. In these two studies they found no difference in drop out rate or use of the primary substance between methadone and buprenorphine in the pregnant women. Also, the APGAR and neonatal abstinence syndrome results for both trials were similar both showing that there was no statistically significant difference between methadone and buprenorphine.[3] With the current guidelines indicating methadone as the treatment of choice for opioid addicted women who are pregnant, and there being a lack of data which favors the use of buprenorphine during pregnancy it is recommended that methadone continue to be the treatment of choice for opioid addiction during pregnancy.

Counseling

Many trials have found a correlation between the use of behavioral counseling and improved treatment outcomes in opioid addiction. While the amount and specific focus of the counseling sessions remains unclear. The general thought is that patients will require more counseling at the beginning of treatment, and that most patients may only need counseling once a week, or even once a month after being stabilized on suboxone.[4] There is some evidence to support counseling aimed at increasing a patient's motivation with an emphasis on improving coping/relapse prevention skills to increase patient outcomes.[5] The general consensus it that the most important aspect is that the patient is receiving counseling while on suboxone in order to help patients to avoid relapse and improve the likelihood of long-term treatment success.[4]

Approval Criteria

- Diagnosis equals Opioid Drug Dependence in last two year
- Physician has Substance Abuse and Mental Health Services (SAMSA) Waiver
- Patient must be under the care of one primary physician
- **Adequate trial and failure on Brand Name Suboxone Tablets/Film**

Denial Criteria

- Lack of approval criteria
- Patient has Suboxone and Benzodiazepine prescribed by 2 different physicians
    - Refer to State Clinical Consultant to determine if benefit outweighs risk
- Pregnancy

References

1. Jones H. "Practical Considerations for the Clinical Use of Buprenorphine." Science & Practice Perspectives (4). August 2004.

2. U.S. Dept of Health and Human Services Publication No. (SMA) 04-3939. TIP 40. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment ; 2004.

3. **Minozzi S, Amato L, Vecchi S, et al. "Maintenance agonist treatments for opiate dependent pregnant women." Cochrane Database Syst Rev. 2008 Apr 16; (2): CD006318.**

4. **Reckitt Benckiser Pharmaceuticals Inc. "Optimizing Your Counseling." 2007. http://www.suboxone.com/patients/suboxone/optimizing_counseling.aspx.**

5. **Copenhaver M, Bruce D, Altice F. "Behavioral Counseling Content for Optimizing the Use of Buprenorphine for Treatment of Opioid Dependence in Community-Based Settings: A Review of the Empirical Evidence." Am J Drug Alcohol Abuse. 2007; 33(5): 643-54.**

Appendix A

Substance Abuse or Mental Health Treatment Services HCPCS or Procedure Codes for Clinical Consultant Review :

Condition	Submitted HCPCS or Procedure Codes	History Date Range
Behavioral Health Counseling & Therapy (15 min)	H0004	730 days
Alcohol & or Drug Services; Group	H0005	730 days
Behavioral Health Day Treatment (per hour)	H2012	730 days
Alcohol & or Substance Abuse Services (Family/Couples)	T1006	730 days
Individual Psychotherapy (Office or Outpt Facility) 20-30 min	90804	730 days
Individual Psychotherapy (Office or Outpt Facility) 45-50 min	90806	730 days
Family Psychotherapy (with patient present)	90847	730 days
Group Psychotherapy (Other than of a multiple-family group)	90853	730 days
Individual Psychotherapy (Inpt or Partial Hosp or Res Care Setting) 20-30 min	90816	730 days
Individual Psychotherapy (Inpt or Partial Hosp or Res Care Setting) 45-50 min	90818	730 days
Individual Psychotherapy (Office or Outpt Facility) 20-30 min w/ Medical Eval & Mgmt Services	90805	730 days
Individual Psychotherapy (Office or Outpt Facility) 45-50 min w/ Medical Eval & Mgmt Services	90807	730 days
Individual Psychotherapy (Inpt or Partial Hosp or Res Care Setting) 20-30 min w/ Medical Eval & Mgmt Services	90817	730 days
Individual Psychotherapy (Inpt or Partial Hosp or Res Care Setting) 45-50 min w/ Medical Eval & Mgmt Services	90819	730 days