TREATMENT POLICY # 03

SUBJECT: Buprenorphine

ISSUED: **August 2004, revised June 6, 2006**

EFFECTIVE: September 1, 2004, revision effective October 1, 2006

PURPOSE:

This policy establishes standards for the use of buprenorphine when used as adjunct therapy in the treatment of opioid addiction for clients receiving substance abuse services administered through the Michigan Department of Health & Human Services, Office of Recovery Oriented Systems of Care (MDHHS/OROSC). PIHPs are required to provide additional reports so the overall cost and experience gleaned from the use of buprenorphine as adjunct to treatment can be used to determine future planning and policy.

SCOPE:

PIHPs may choose to fund the cost of the buprenorphine/naloxone medication as adjunct therapy for opioid addiction in treatment services including residential, intensive outpatient, outpatient, and methadone programs. Allowable funding consists of federal block grant, state general funding, and local funding. Medicaid reinvestment savings may also be used if part of a Medicaid reinvestment plan submitted by the Pre-paid Inpatient Health Plan (PIHP) and approved by Centers for Medicare and Medicaid Services (CMS) and MDHHS/OROSC. PIHPs may use clients on a discretionary basis after covered services have been paid.

Clients with Medicaid coverage may have access to the pharmacy benefit for buprenorphine/naloxone. It must be preauthorized through the Medicaid pharmacy plan.

Opioid Treatment Programs (OTPs) providing services must conform to the Federal opioid treatment standards set forth under 42 C.F.R. Part 8, including off-site dosing when dispensing buprenorphine/naloxone. There is no limit to the number of clients to whom buprenorphine can be dispensed from an OTP.

Private physicians who have the Substance Abuse and Mental Health Services Administration (SAMHSA) waiver for prescribing buprenorphine/naloxone are limited to managing 30 clients on buprenorphine at any one time. An OTP physician who has the SAMHSA waiver may prescribe the medication for off-site use as if the physician were in private practice. The maximum number of active clients would be 30 clients.

BACKGROUND:

The Food and Drug Administration (FDA) approved Buprenorphine hydrochloride (Subutex®) and buprenorphine hydrochloride/naloxone hydrochloride (Suboxone®) on October 8, 2002 for the treatment of opioid addiction. Both buprenorphine and buprenorphine/naloxone are administered in sublingual tablets (placed under the tongue) and gradually absorbed. Prior to their approval and subsequent scheduling as Schedule III medications, the only prescription medications approved for opioid substitution agents were methadone and LAAM, both Schedule II medications. Schedule II medications must be prescribed to patients enrolled in OTPs. Because of the numerous federal and state regulations with respect to OTPs, the addition of Schedule III medications as adjunctive treatment greatly increases access to services for potential opioid treatment clients because they can now receive medication for opioid addiction treatment through a qualified physician's office.

Buprenorphine has a ceiling effect for toxicity because of its antagonist properties. Once a certain dose or receptor occupancy level is reached, additional dosing does not produce further toxicity. Studies have shown that buprenorphine plateaus at the equivalent of 40 to 60 milligrams of methadone. Because of the maximum for toxicity, respiratory depression and/or death from overdose are less common than with opiate agonists, such as heroin, oxycodone, or methadone. Concurrent use of buprenorphine with alcohol, benzodiazepines, or other respiratory depressants can still result in overdose. Naloxone (Narcan) is added to buprenorphine by the manufacturer to prevent diversion because, although the naloxone will have no effect when absorbed under the tongue, crushing and injecting the medication will result in sudden and intense withdrawal symptoms. The ceiling effect also restricts the medication's effectiveness in treating patients who have a need for high levels of opioid replacement medication. Studies are currently being done to determine the safety of buprenorphine/naloxone in pregnancy as well as breastfeeding.

REQUIREMENTS:

Program Requirements

1. The client must have a Diagnostic Statistical Manual (DSM) impression of opioid dependency as determined by the Access Management System (AMS). All six dimensions of the current American Society of Addiction Medicine (ASAM) Patient Placement Criteria must be used. The client must meet medical necessity criteria as determined by a physician who has a SAMHSA waiver to prescribe or dispense buprenorphine.

2. Buprenorphine/naloxone must be used as adjunct to opioid treatment throughout the continuum of care (OP, IOP, Residential, sub-acute detoxification, and methadone adjunctive treatment as part of a detoxification regimen). It cannot be used without counseling.

3. Toxicology screens must be done at intake and then on a random, at least weekly, frequency until three (3) consecutive screens are negative. Thereafter, they must be done on a monthly, random frequency. Screens must assay for opioids, cocaine, amphetamines, cannabinoids, benzodiazepines, and

methadone metabolites. Screens must be random for days of the week and days since last screen was administered.

4. As an adjunctive medication for the treatment of opioid addiction, the PIHP cannot pay for the buprenorphine/naloxone alone. The medication must be used in conjunction with counseling at a substance abuse treatment program under contract with the PIHP. The PIHP must develop a plan in which the substance abuse treatment program, a qualified physician, and a pharmacy are involved.

Reporting Requirements

The data system has been modified to accommodate reporting for clients receiving buprenorphine/naloxone.

Data system:

- **Admission and discharge Treatment Episode Data Set (TEDS) records must be submitted as is routine with other clients. In the client admission record, the field OPIOD TREATMENT PROGRAM (1= Methadone, 2= No, and 3= Buprenorphine) must be coded with "3" for all clients receiving buprenorphine/naloxone, regardless of service category.**
- **Buprenorphine/naloxone daily dosages and associated cost must be reported with HCPCS Code of H0033 as required in the 837 Professional Encounter record.**

PROCEDURE:

Prescribing Policy

1. All physicians, including those at an OTP, must have a waiver from SAMHSA permitting them to prescribe or dispense buprenorphine/naloxone (e.g., Suboxone®).

2. Buprenorphine/naloxone (Suboxone®) must be used as an adjunctive treatment within an individualized treatment plan for opioid addiction. It is not appropriate as a stand-alone treatment procedure.

3. The target populations for buprenorphine/naloxone are the following:

- Clients who are being transferred from methadone as part of a detoxification regimen;
- Clients that have been opioid dependent less than one year, but for whom adjunctive therapy is deemed medically necessary; and
- Clients that are eligible for methadone adjunctive therapy within the 40-60 milligrams therapeutic range.

4. In accordance with FDA regulations, buprenorphine is not currently approved for pregnant women.

5. The combination medication buprenorphine/naloxone (Suboxone®) is the only medication approved for use under these guidelines. No "off-label" or experimental use of buprenorphine/naloxone is permitted under these policies.

REFERENCES:

American Psychiatric Association. (2000). *The Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Text Revision, Washington, DC.

American Society of Addiction Medicine. (2001). *ASAM Patient Placement Criteria for the Treatment of Substance-Related Disorders*, Second Edition-Revised, ASAM UPC-2R, Chevy Chase, Maryland.

Certification of Opioid Treatment Programs: United States Code of Federal Regulations, Title 42, Part 8, Washington, D.C. (2003).

Drug Addiction Treatment Act of 2000: PL106-310, Section 3502, United States House, 105th Congress, Washington, DC. (October 17, 2000).

Food and Drug Administration. (October 8, 2002). *Subutex and Suboxone Approved to Treat Opiate Dependence*, FDA Talk Paper, Washington, DC.

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Addition of Buprenorphine and Buprenorphine Combination to List of Approved Opioid Treatment Medications: Federal Register, Volume 68, Number 99, pp 27937-27939, Interim final rule, United States Superintendent of Documents. (May 22, 2003).

Schuster, C and Seine, S. (October 8, 2002). *Interview*. University Psychiatric Clinic, Wayne State University, Detroit Michigan.

APPROVED BY: ___*SIGNED*_____

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