ASAM
American Society of Addiction Medicine

Public Policy Statement on Office-based Opioid Agonist Treatment (OBOT)

BACKGROUND

Methadone maintenance treatment of opioid addiction was developed in 1965 and implemented in the United States as a form of opioid agonist treatment. In the 1970s, a system of federal regulation was imposed in response to reports of diversion of methadone into illicit channels. In 1993, the US government gave approval to LAAM as a second maintenance medication, and, in 2002, buprenorphine, a partial agonist with an improved safety profile, was approved for limited office use by specially qualified physicians. [See ASAM Public Policy Statements: Methadone Treatment, rev. 1991, and Buprenorphine for Opiate Dependence and Withdrawal, rev. 2002.]

When methadone maintenance, administered in licensed and accredited Opioid Treatment Programs (OTPs), is integrated with a comprehensive treatment service including individual and group psychotherapies and ancillary services such as occupational counseling, it has an efficacy and safety profile that has been solidly and repeatedly established in the clinical outcomes literature since 1965. Several distinguished bodies and consensus panels (e.g., NIH Consensus Statement 1997) have summarized this evidence and called for more access to this modality. Additionally, there is a growing European and North American literature supporting the efficacy and safety of office-based treatment with buprenorphine and methadone. Heroin addiction and addiction to prescription opioid analgesics are growing problems in the US, and the need for increased availability of effective treatment is clear.

Methadone maintenance treatment has been a significantly underutilized treatment modality in the US. Opioid agonist treatment programs reach only about 1/4th of the estimated 800,000 regular heroin users. In 2003, there were no Opioid Treatment Programs at all in five US states, and, in several other states, individual counties bar this treatment modality.

Treatment is underutilized at a time when the need for it is increasing: there is an increased availability of unusually pure and cheap heroin that can be profoundly addicting in intranasal and smokeable forms; heroin use is growing particularly rapidly among the young; and, there is a rising incidence of addiction to prescription opioid analgesics.

DEFINITIONS:

1. Opioid Treatment Programs (OTPs):

Licensed and accredited opioid agonist treatment programs, often called methadone maintenance treatment (MMT) programs, are currently authorized to dispense methadone, LAAM, and buprenorphine in highly structured protocols defined by Federal and State law and

regulation.[1] By regulation, patients must earn take-home medication privileges by demonstrating, via urinalysis or other drug testing, that they are free of illicit drugs, and by demonstrating cooperation with other treatment requirements. Research has shown that the best outcomes are found when medication (methadone) is combined with psychosocial treatments. Over time, many patients graduate to less structured services, with medications dispensed in weekly to (at most) monthly take-home quantities. The frequency and intensity of psychosocial services should vary according the phase of care, determined by patient progress and needs.

2. Office-Based Opioid Agonist Treatment (OBOT):

OBOT refers to models of opioid agonist treatment that seek to integrate the treatment of opioid addiction into the general medical and psychiatric care of the patient**.** The foundation of OBOT is the conceptualization of opioid addiction as a chronic medical condition with similarity to many other chronic conditions. An important feature of OBOT is that it allows primary care physicians to provide addiction treatment services in their usual clinical settings, thus expanding the availability of care.

OBOT can refer to treatment with methadone (a Schedule II medication) or with buprenorphine (a Schedule III medication). At present, only two medications (both formulations of sublingual buprenorphine) meet the requirements of the authorizing law, the *Drug Abuse Treatment Act of 2000* (DATA 2000). DATA 2000 provides for a model of OBOT by authorizing Schedule III-V medications to be used by qualified physicians in their offices for the treatment of opioid dependence or opioid addiction if those medications have been approved for this indication and if the physician has "the capacity to refer the patients for appropriate counseling and other appropriate ancillary services**."**

Several different models of OBOT have been tested in the US and in other countries. In a US model of OBOT usually called *Medical Maintenance*, there is a close affiliation between the office practice and the OTP that refers stable patients and continues to offer ancillary psychosocial treatment services as needed. In this model, exemptions must be requested by OTPs, and OBOT physicians must be affiliated with a sponsoring OTP.

European and Canadian models of agonist care are significantly less restrictive because they are not OTP clinic-based. Patients may be admitted and entirely managed in the physician's office with periodic visits, drug testing, and medication management. In the Canadian model, for example, agonist medications are dispensed as frequently as daily from a collaborating pharmacy, and, in addition to physician visits, patients participate in community-based psychosocial care. In such models physicians work relatively independently of OTPs.

3. Treatment Components, Structure and Intensity:

Examples of treatment *components* include counseling (individual and group), general medical care, psychiatric services, programs for family members, educational/vocational counseling, financial counseling, and legal services.

Treatment *structure* refers to elements such as the requirements a patient must meet in order to continue in treatment. Examples of such requirements are attendance compliance, no use of illicit drugs, and participation in psychosocial services.

[1] In 2003, the manufacturer of ORLAAM©, Roxane Pharmaceuticals, announced that it was ceasing production and distribution of the product and expected supplies to be depleted by February 2004. The remainder of this Public Policy Statement, therefore, refers only to methadone and buprenorphine.

Treatment *intensity* refers to the number of treatment components the patient utilizes (each of which can range from less to more rigorous) and the frequency with which the patient participates. For example, the frequency of counseling sessions can vary from one per day to one per month; the length of counseling session can range from ten minutes to one hour; the type of counseling can range from classroom sessions to those where the patient engages in an active role with the counselor.

Current US models of opioid agonist treatment rely on providing access to psychosocial services such as group therapy, patient education classes, relapse prevention services, mental health care, access to medical diagnostics and care, and randomized urine drug testing. Generally speaking, unstable patients in early treatment require both more structured treatment and greater intensity of such services than patients who are stable and have embraced a recovery-oriented lifestyle.

However, in areas where such services are not available, such as areas where there are no OTPs, pharmacological treatment alone with support of the treating clinician may still represent an important option for some patients.

Rationale for Expansion of Office-Based Opioid Treatment Programs:

Two formulations of buprenorphine are authorized by the Drug Abuse Treatment Act of 2000 (DATA 2000) for OBOT in the US. Methadone is approved for OBOT in Canada and several European countries, but not in the US. This situation means that whether a patient can be *routinely* treated in an office setting in the US is determined by the Schedule of the medication to be used and the approved indication, not by the clinical circumstances of the patient.

The decision to provide OBOT should not have to be made on the choice of the opioid agonist medication to be used. The selection of an opioid agonist treatment program, like the selection of any modality of treatment, should be based upon a multidimensional assessment of the patient's severity of illness, matching intensity and structure of treatment (level of care), using objective criteria such as those found in ASAM's Patient Placement Criteria, Second Edition Revised (ASAM PPC-2R).

Some opioid-addicted patients can be treated effectively with buprenorphine; others will require methadone. Some, particularly those new to treatment, may require highly structured treatment programs involving on-site, observed administration and dispensing of medication such as is utilized in OTPs, combined with intensive psychosocial and adjunctive therapies. Other patients do well in less structured settings and with a lower level of psychosocial services. The needs of patients change as their time in treatment lengthens and as they accomplish treatment goals and life changes associated with recovery. One size does not fit all, and ASAM strongly supports the need for a full continuum of service, linked to psychosocial stability, results of urine drug tests, and other patient-progress criteria.

ASAM believes that the level of structure and intensity of services in treatment programs in which patient are initiated on opioid agonist treatment with methadone should be higher than in programs treating stable patients. ASAM believes that appropriate levels of structure and intensity of services can be maintained by OBOT programs as well as by OTPs. For example, OBOT programs can have observed administration of medication, and psychosocial recovery resources, and trained and qualified OBOT physicians, knowledgeable about treating opioid addiction.

ASAM's policy recommendations seek to simplify current procedures for providing

Medical Maintenance for stable patients, encourage increased use of federal regulatory exemptions to test other innovative strategies for expanding access to methadone, permit OBOT physicians to change from Schedule III opioid agonists to Schedule II opioid agonists when buprenorphine is not able to "hold" the patient, and support public and private insurance coverage for Office Based Opioid Treatments.

ASAM Policy Recommendations:

1. Clinical Guidelines:

Physicians who provide office-based opioid agonist treatment (OBOT) should take into consideration clinical guidelines related to that treatment. Such guidelines should reflect research findings, best practices, and the consensus of experts in the field of opioid addiction treatment.

***ASAM recommends* development of OBOT practice guidelines through collaboration among addiction medicine and addiction psychiatry organizations.**

2. Physician Training:

Specific training should be required for physicians to qualify for approval to provide office-based opioid treatment using opioid agonists. Clinical use of buprenorphine requires certification in addiction medicine or addiction psychiatry, or 8 hours of specialized training, and receipt of a unique DEA number. The different safety profile of methadone compared with buprenorphine calls for additional specific training for physicians to be authorized to provide office-based opioid treatment with this medication.

***ASAM recommends* that physicians in office-based settings who treat patients for opioid dependence or opioid addiction using Schedule II medication (methadone) should be required to have completed a one-time training, over a 2-year period, consisting of 16 hours of accredited Category 1 continuing medical education (CME) specific to opioid pharmacotherapy with methadone. The content should be specified in practice guidelines developed through collaboration among addiction medicine and addiction psychiatry organizations.**

No part of this requirement would be met by the training described in Drug Abuse Treatment Act of 2000 to qualify physicians to use the Schedule III-V medications approved for treatment of opioid dependence (sublingual buprenorphine).

3. Continuum of Care:

ASAM recognizes the place that Opioid Treatment Programs (OTPs) hold in the continuum of care by providing highly structured treatment environments. The clinical, social, and public health benefits of methadone maintenance administered in federally licensed and accredited Opioid Treatment Programs have been repeatedly demonstrated in clinical research studies and are irrefutable. In addition, recent studies of Medical Maintenance support feasibility and efficacy of transferring stable patients to office-based physician care.

ASAM recognizes that "graduating" stable patients who wish to transfer from OTPs to office-based maintenance may increase the severity and complexity of the remaining patient mix within OTPs. Nonetheless, it is consistent with usual standards of medical practice to provide the least restrictive environment appropriate to the nature and stage of a patient's illness.

ASAM recognizes that patients who prove unstable in office settings will require the level of structure and intensity of integrated services available in an OTP if a higher level of structure cannot be obtained in the OBOT setting. It is essential that

referrals occur in both directions, i.e., that patients have the capacity to be "stepped-up into OTP" as well as "stepped-down to OBOT" based on clinical criteria.

ASAM recognizes that patients who require a higher level of service intensity consume more resources and that higher levels of funding are needed to support appropriate treatment for such complex patients.. Without a proportional increase in funding to match the intensity of service, there might be a *de facto* disincentive for OTPs to refer stable patients to the next lower level in the continuum of care.

***ASAM recommends*:**

(a) That all OTPs have the capacity to "graduate" a patient to Medical Maintenance when that level of care is indicated.

(b) That OBOT physicians, affiliated or independent, and OTPs establish a collaborative relationship that permits patients to be referred back and forth between programs, providing differing models and intensities of treatment, according to clinical needs.

(c) That reimbursement levels be more closely linked to the level of care provided: more intensive, more complex and time-consuming services should be reimbursed at higher rates.

4. Expansions of Office-Based Agonist Treatment:

(a) Medication Changes from Schedule III to Schedule II:

Currently, buprenorphine is the only agent approved for prescription by qualified physicians in office-based management of opioid dependence or opioid addiction. Although each qualified physician (or group practice) is currently limited to 30 patients, OBOT with buprenorphine does represent an expansion of treatment availability.

Not all patients who begin opioid agonist treatment on buprenorphine in an OBOT setting under DATA 2000 provisions can be satisfactorily managed on buprenorphine, and some will require a transfer to methadone. ASAM supports allowing trained and qualified physicians to change the agonist medication from buprenorphine to methadone when indicated.

***ASAM recommends* that, as a further expansion of office-based agonist maintenance treatment, federal law and regulation be revised to authorize use of Schedule II medication (methadone) by appropriately trained and qualified physicians for patients who were started on buprenorphine under DATA 2000 when a change in medication is clinically indicated.**

(b) Medical Maintenance Simplification:

Current federal regulations provide for exemptions for Medical Maintenance to be available only through OTPs. ASAM believes that knowledgeable and trained physicians can provide Medical Maintenance treatment without having a contractual or agent relationship with an OTP.

ASAM recommends that federal law and regulations be revised to

(1) Endorse Medical Maintenance as an advanced, but routine, component of OTPs.

(2) Eliminate the need for OTPs to apply for a regulatory exemption for Medical Maintenance.

(3) Make waivers available to qualified physicians to provide Medical Maintenance Treatment independent of an OTP.

5. Insurance Coverage:

Opioid addiction and opioid dependence are medical illnesses defined in DSM-IV and ICD-10. High proportions of patients with heroin addiction have co-occurring disorders such as HIV, hepatitis B and C, soft tissue infections, and psychiatric disorders. Early and combined treatments will provide cost offsets against later, more expensive, medical services.

ASAM recommends **public and private medical insurance coverage for treatment of opioid addiction or opioid dependence in both office-based settings and in Opioid Treatment Programs.**

ASAM recommends **that public and private insurers provide adequate reimbursement for both the pharmacotherapeutic and psychosocial components of addiction treatment because each is an essential element in recovery that reduces long-term medical costs.**

6. Demonstration Projects & Regulatory Exemptions:

Innovative projects evaluating a variety of treatment delivery strategies are needed in order to allow meaningful and measured expansions of access to treatment. Such projects can be especially important in medically underserved areas, in rural areas and other parts of the country that currently do not have access to OTPs.

Transfer of stabilized OTP patients to Medical Maintenance in office-based settings was initially available to physicians via an Investigational New Drug (IND) application only. In 2000, this was made available, via application to CSAT, through the OTP program-wide exemption provisions of 21 CFR §291.505(d)(11). As of December 2002, five exemptions had been authorized; three publications from these sites reported feasibility, reasonable retention rates, comparable outcomes to OTPs, and a high level of physician and patient satisfaction. ASAM believes that Medical Maintenance has been adequately tested and should now be endorsed as a routine service component of OTP programs (and no longer require application for exemption).

It is also important to evaluate the feasibility and efficacy of direct admissions to OBOT methadone maintenance programs as is done in France and Canada. There are data from such studies conducted in other countries; studies should evaluate analogous treatment models under conditions in the US.

ASAM recommends that federal regulations provide for exemptions to study models other than Medical Maintenance, especially models that incorporate elements of structure appropriate to support patients new to treatment. Future regulatory exemptions should focus on other methods of expanding access to methadone. There is a great need to test European and other models that expand access to opioid agonist medications. For example, rural and underserved areas may not have OTPs within reasonable driving distances, and models of OBOT opioid agonist treatment need to be tested in such locales.

ASAM recommends **that SAMHSA/CSAT develop rules and procedures for granting regulatory exemptions for demonstration projects designed to evaluate the safety and efficacy of direct admissions to OBOT using methadone and innovative models of treatment delivery, especially in currently underserved areas.**

ASAM recommends **additional federal funding and technical support for demonstration projects in community settings.**

ASAM recommends **federal funding to implement and evaluate these models.**

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