Opportunity for Expansion of OUD Medication Assisted Treatment within OTPs by Incorporating Extended Release Naltrexone

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Opioid Treatment Programs (OTP) serve approximately 300,000 people nationally and provide critically needed treatment for those with Opioid Use Disorders (OUD). Since the Narcotic Addict Treatment Act of 1974 authorizing methadone maintenance treatment outside of research environments the ability to provide scientifically established and recovery supportive treatment has grown. The Drug Addiction Treatment Act (DATA) of 2000 followed by federal regulatory changes in 2013 enhanced the potential to expand medication options from methadone alone to buprenorphine integration within Opioid Treatment Programs thereby expanding treatment options for patients. While methadone and buprenorphine are the most strongly supported evidence based treatment options available with longstanding well established efficacy and safety profiles the continued expansion of available treatments is supported by COMPA.

In 2010 the FDA approved the use of extended release naltrexone (Vivitrol) for the treatment and prevention of relapse of an OUD. Naltrexone is an antagonist of the mu opioid receptor and serves to block the effect of opioids. While it is available in an oral formulation which can be taken daily, the FDA approval for treatment of an OUD is limited to the extended-release formulation which is a once a month injectable medication. In addition to clinical data supporting extended release naltrexone, findings also suggest a significant interest among opioid users for its use as well.

OTPs have valuable clinical experience and an established organization to provide medication assisted treatment which may be able to support the integration of extended release naltrexone. OTPs considering the implementation of extended release naltrexone are encouraged to review and develop additional administrative and clinical policies such as those related to clinical differences when utilizing a long-acting antagonist injectable medication, medication procurement and storage, health insurance benefit management, and others. A multi-disciplinary team approach led by the Medical Director is encouraged.

The following examples highlight a few of the clinical differences related to opioid antagonists. Completion of a detoxification process is required for anyone with a current physiologic dependence prior to the use of extended release naltrexone. A low dose antagonist challenge may also be needed after the detoxification process especially if a person has been on long acting opioids such as methadone. The duration of the detoxification process may vary significantly as it is dependent on a number of medical considerations and patient preference. Also as compared to agonist medications which retain a person's opioid tolerance, the use of an antagonist such as Vivitrol does not. Therefore patients utilizing antagonist treatment have very low to no opioid tolerance and if discontinue medication and relapse to opioid use they may be at significantly higher risk for an adverse event such as overdose. Additional procedures may be indicated to closely monitor for adherence to scheduled monthly medication visits, adverse events, and to identify medication contraindications such as pregnancy. The medication procurement and health insurance reimbursement processes also vary and may require administrative coordination.

Due to the various aforementioned clinical and administrative differences patient selection is of significant importance. Criteria to consider may include patient preference to utilize antagonist instead of highly efficacious agonist medication, patient stability to anticipate regular monthly attendance for medication, no medical contraindications such as pregnancy or need of medically indicated opioids for pain control,

ability to complete opioid detoxification and antagonist induction process, patient treatment goal of full abstinence of all opioid use, health plan support, and clinical assessment indicating OTP level of care. Some examples of those who may benefit from the availability of extended release naltrexone in an OTP include patients already enrolled in OTPs but are tapering off agonist medications, those no longer on agonist medication but remain in aftercare treatment, and others.

COMPA recognizes the need for additional research to identify implementation strategies, patient selection criteria, and outcome data relevant for OTPs and our patient population. Consideration of extended release naltrexone within OTPs is supported by COMPA as an evidence based and FDA approved treatment option for select patients with opioid use disorders.