HEALTHWEST

Procedure

No. 06-030

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Approved by:

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Subject: Vivitrol Administration Protocol

I. PURPOSE

It is the commitment of HealthWest to provide quality health care that includes addiction treatment, with patient safety as a priority.

II. APPLICATION

All HealthWest employees, volunteers, student interns, interpreters, affiliated providers, and persons under contract with HealthWest.

III. PROCEDURE

A. Vivitrol is a form of Naltrexone, indicated for the treatment of either opiate or alcohol dependence. Prior to utilizing Vivitrol, an opioid-free duration of a minimum of 7 days, Suboxone-free for 12 days, Methadone-free for 14 days and 24-48 hours alcohol-free is recommended for patients, per provider's discretion, to avoid precipitation of withdrawal that may be severe enough to require hospitalization. A single injection of 380 mg is effective for 30 days, so subsequent injections should be timed at every 28 days. Vivitrol should be part of a comprehensive management program that includes psychosocial support.

B. Vivitrol is contraindicated in:

1. Patients receiving opioid analgesics.

2. Patients with current physiologic opioid dependence.

3. Patients in acute opioid withdrawal.

4. Any individual who has failed the naloxone challenge test or has a positive urine screen for opioids.

5. Patients who have previously exhibited hypersensitivity to any component of vivitrol or component of the diluents.

6. Relative contraindication – Pregnancy Category C – use with caution. The risk of using the treatment or procedure is acceptable when the benefits outweigh the risks

C. Program Availability

Vivitrol administration will be available at each of HealthWest's physical clinic location. Vivitrol can be administered by registered nurses at HealthWest.

D. Initial Assessment

1. Establish the diagnosis of opiate/alcohol addiction, including the duration, pattern and severity of opioid misuse; the patient's level of tolerance; results of previous attempts to discontinue opioid use; past experience with agonist therapies; the nature and severity of previous episodes of withdrawal; and the time of last opioid/alcohol use and current withdrawal status, as documented on the Substance Use Assessment (C311).

2. Document the patient's use of other substances, including alcohol and other drugs of abuse.

3. Identify comorbid medical and psychiatric conditions and disorders to determine how, when and where they will be addressed.

4. Screen for communicable diseases and address them as needed, inclusive of HIV testing. Evaluate the patient's level of physical, psychological and social functioning or impairment.

5. Assess the patient's access to social supports, family, friends, employment, housing, finances, and legal problems.

6. Determine the patient's readiness to participate in treatment.

7. Pregnancy test for all women of childbearing age shall be completed at baseline and at the prescriber's discretion.

8. Physical exam, should focus on evaluating neurocognitive function, identifying sequelae of opioid/alcohol addiction, and looking for evidence of severe hepatic dysfunction. Appropriate laboratory screenings will be conducted.

9. Urine drug screens or other toxicologic screens should be part of the initial evaluation to confirm recent opioid/alcohol use and unreported use of other drugs.

   (This drug screen should include all opioids commonly prescribed and/or misused in the local community, as well as illicit drugs available locally. This will be reviewed annually and as needed by the Medical Director.)

10. Access the patient's prescription drug use history through the state's prescription drug monitoring program (MAPS), both to confirm compliance in taking prescribed medications and to detect any unreported use of other prescription medications. Assessment continues throughout treatment. A MAPS will be completed based on the state law Public Act 248 of 2017 A MAPS will be completed based on the state law Public Act 248 of 2017 before prescribing or dispensing controlled substances.

11. Vivitrol consent and the Medication Assisted Treatment Agreement (C363) must be signed and documented as signed in the eHR/electronic prescribing system.

12. Insurance coverage/prior authorization must be confirmed prior to administration of the injectable.

Deductibles and co-pays would be the responsibility of the individual.

E. Follow up Appointments

Follow up for patients: Follow up months 1 – 3 must include a medication review and drug screen monthly, combination of group and individual session at least one time per week. Months 4 and on the medication review and drug screen and the group and individual sessions as recommended within the person session plan. The Cravings Assessment (Form C377) will be completed and reviewed with the prescriber at these contacts.

F. Standing Orders

1. Liver function test will be ordered to be done within 1 month for new patients and results are within acceptable range per provider's review and discretion. Subsequent LFT's should be completed every three (3) months, per provider discretion. Refer to Appendix G.

2. Standing order for pregnancy test as appropriate.

3. Standing order for point of care testing to confirm negative for opiates.

4. MAPS to be completed each time Vivitrol is ordered and more frequently at the provider's discresion.

G. Patient Tracking

Each site will designate one staff person for patient tracking and follow-up (generally a Case Worker). The designated staff will be responsible for following up with the patient to provide appointment reminders, determine if appointments are kept, and verify attendance at counseling sessions.

H. Vivitrol Administration

1. Confirm that Vivitrol consent and the Medication Assisted Treatment Agreement (C363) are signed.

2. The RN or LPN will verify with the patient that he/she has been opioid-free for a minimum of seven (7) days, Suboxone-free for a minimum of twelve (12) days and Methadone-free

for at least fourteen (14) days and/or alcohol-free for 24-48 hours (per provider discretion), prior to administration of injection. This documentation will be noted on the current lab results by affixing the vivitrol label (found in the lab).

3. RN to perform and document pregnancy test, if appropriate. Verify negative result. If pregnancy test is positive, consult provider.

4. RN to perform point of care testing to confirm negative for opiates. Client must remain on site until the testing process is completed. Client shall remain onsite unless accompanied by a HealthWest staff member. If the client leaves the testing site treatment will be terminated. If test is positive consult provider.

5. Oral Naltrexone to be initiated after acute withdrawal from opioids.

    a. There should be a 7 day opioid-free period for short-acting opioids and 7 - 10 day period for long-acting agents.

    b. The first does of naltrexone is typically preceded by a naloxone challenge test to assure the absence of any precipitated withdrawal symptoms prior to administering naltrexone. The initial does of naltrexone used generally is 25 mg on the 1st day, followed by 50 mg daily or an equivalent of 350 mg weekly, divided into three doses (100, 100, 150 mg). The principal reason for the reduced dose on day 1 is the potential for gastrointestinal side effects, such as naseau and vomiting.

    c. After 3 days of oral naltrexone, the Vivitrol injection may be administered.

6. Vivitrol will be reconstituted and administered per manufacturer's instructions, using only components provided by the manufacturer.

IV. REFERENCES

MDCH Medication Assisted Treatment Guidelines for Opioid Use Disorders, Corey Waller MD, MS

CB/ab

HEALTHWEST

MEDICATION ASSISTED TREATMENT AGREEMENT

Date: _____ Case Number: _____

Name: _____

As a participant receiving medication assisted treatment for a substance use disorder, I freely and voluntarily agree to accept this treatment agreement/contract as follows:

(Please initial the below statements as they are reviewed by and/or read to you.)

☐ I agree to keep, and be on time to, all my scheduled appointments with my physician and/or physician assistant/nurse practitioner.

☐ I agree to not sell, share, or give any of my medication to another individual.

☐ I agree that my medication will be provided at scheduled appointments; missed appointments may result in a delay in receiving medication. Medication will be provided to take home in quantities based on individual assessment. Random call-backs to verify counts (including wrappers) will occur. I will respond to call-backs within 48 hours.

☐ I agree that the medication I receive is my responsibility and that I will keep it in a safe, secure place. I agree that lost medication will not be replaced regardless of the reasons for such loss.

☐ I agree to not obtain medications from any physicians, pharmacies, or other source outside of HealthWest without informing my treating physician. I understand that mixing buprenorphine with other medications, especially benzodiazepines such as valium, alcohol, and other drugs of abuse can be dangerous and even deadly.

☐ I agree to take my medication as prescribed, inclusive of all prescribed medications, and will not alter the way I take my medication without consulting with my doctor first. I will stop taking all other opioid medications unless explicitly told to continue.

☐ Urine, Saliva, and Serum Drug Screens will be completed on a regular and random basis; visual observation by staff may be required.

☐ I understand that medication alone is not sufficient treatment for my disease, and I agree to participate in the recommended treatment program to assist in my treatment. The recommended treatment program consists of the following:

Week 1 – 4:

- Weekly Medication Review
- Weekly individual session with member of the multidisciplinary treatment team for MAT monitoring
- Weekly Drug Screen
- Weekly Group Therapy
- Attend a 15 minute, free Red Project training and obtain a Naloxone kit by this date: _____

Week 5 – 12:

- Weekly Individual session with treatment team
- Weekly Drug Screen
- Weekly Group Therapy

- Monthly Medication Review at a minimum or as determined by the provider

Week 13/Month 4 – Month 6:

- Month Medication Review or as determined by the provider
- Monthly Drug screen or as determined by the provider
- Combination of Group and Individual sessions at least one time per week

Month 7 and on:

- Medication review 1 – 3 times every 90 days
- Drug screen 1 – 3 times every 90 days
- Group and Individual sessions as recommended within Person Centered Plan

☐ If, after MAT treatment begins, a consumer has a positive drug screen, tests negative for Buprenorphine, or if films have not been picked up on a consistent basis, they will be switched to on-site dosing. After the first instance dosing will be on-site for 1 week. After the 2nd offense, dosing will be on-site for two weeks. Following it will then re-evaluated by the prescribing physician as necessary. If on-site dosing is unsuccessful, an injectable dose of Sublocade will be required.

By signing below you indicate that you have reviewed and agree to the above guidelines and all questions relating to these guidelines have been addressed with a member from your treatment team.

_____ _____
Consumer Signature Date

_____ _____
Treatment Team Member Signature Date

A copy of this document was provided to the consumer. ☐

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ACUERDO PARA TRATAMIENTO ASISTIDO CON MEDICAMENTOS

Fecha: _____ Nombre: _____ Número de caso: _____

Como participante que recibe tratamiento asistido con medicamentos por un trastorno de consumo de sustancias, acepto libre y voluntariamente este acuerdo o contrato de tratamiento conforme a lo incluido a continuación:

(Por favor, escriba sus iniciales en las siguientes declaraciones a medida que son revisadas y / o leídas).

☐ Acepto respetar y llegar en hora a todas mis citas programadas con mi médico, mi asistente médico o mi enfermero licenciado.

☐ Acepto no vender, compartir ni regalar mis medicamentos a otra persona.

☐ Acepto que me entreguen mis medicamentos en las citas programadas; si falto a una cita, podría retrasarse la entrega de los medicamentos. Me darán medicamentos para llevarme a casa en cantidades adecuadas según mi evaluación personal. Es posible que me convoquen, aleatoriamente, para verificar el recuento de medicamentos (incluidos los envoltorios). Responderé a esas convocatorias en un plazo de 48 horas.

☐ Acepto que los medicamentos que reciba son mi responsabilidad y los guardaré en un lugar seguro. Acepto que los medicamentos extraviados no serán repuestos, independientemente de los motivos de dicho extravío.

☐ Acepto no recibir medicamentos de ningún otro médico, farmacia u otro tercero ajeno a HealthWest sin informar a mi médico tratante. Entiendo que mezclar buprenorfina con otros medicamentos, en especial las benzodiazepinas (como el Valium), el alcohol y otras drogas ilegales puede ser peligroso e incluso mortal.

☐ Acepto tomar mis medicamentos según lo indicado, inclusive todos mis medicamentos recetados, y no alteraré el modo en que tomo los medicamentos sin antes consultar con mi médico. Dejaré de tomar todos los demás medicamentos opiáceos salvo que me digan explícitamente que siga haciéndolo.

☐ Me harán análisis de orina, saliva y sangre para detección de drogas, tanto periódicamente como en forma aleatoria; tal vez sea necesario que un miembro del personal esté presente como testigo visual.

☐ Entiendo que solo el medicamento no es tratamiento suficiente para mi enfermedad y acepto participar en el programa de tratamiento recomendado que ayudará a mi tratamiento general. El programa de tratamiento recomendado consta de lo siguiente:

Semanas 1 a 4:

- Revisión semanal de los medicamentos.
- Sesión semanal individual con un integrante del equipo de tratamiento multidisciplinario para control de MAT.
- Prueba de detección de drogas semanal.
- Terapia de grupo semanal.
- Asista a una capacitación gratuita de 15 minutos de Red Project y obtenga un kit de naloxona para esta fecha: _____

Semanas 5 a 12:

- Sesión semanal individual con el equipo de tratamiento.
- Prueba de detección de drogas semanal.
- Terapia de grupo semanal.
- Revisión mensual de medicamentos, como mínimo, o según lo determine el proveedor.

Semana 13/mes 4 - mes 6:

- Revisión mensual de medicamentos o según lo determine el proveedor.
- Prueba de detección de drogas mensual o según lo determine el proveedor.
- Combinación de sesiones grupales e individuales al menos una vez por semana.

Mes 7 en adelante:

- Revisión de medicamentos de 1 a 3 veces cada 90 días.
- Prueba de detección de drogas de 1 a 3 veces cada 90 días.
- Sesiones grupales e individuales según las recomendaciones del Plan Centrado en la Persona.

☐ Si, después de que comience el tratamiento con MAT, un consumidor tiene una prueba de detección de drogas positiva, resultados negativos para Buprenorfina, o si las películas no se han recogido de forma constante, se cambiarán a la dosificación in situ. Después de la primera instancia, la dosificación se realizará in situ durante 1 semana. Después de la segunda ofensa, la dosis estará en el sitio durante dos semanas. A continuación, el médico que prescribe lo volverá a evaluar según sea necesario. Si la dosificación en el lugar no tiene éxito, se requerirá una dosis inyectable de Sublocade.

Al firmar a continuación, indica que ha revisado y está de acuerdo con las pautas anteriores y que todas las preguntas relacionadas con estas pautas se trataron con un miembro de mi equipo de tratamiento.

_____	_____	_____	_____
Firma del usuario	Fecha	Firma del miembro del equipo de tratamiento	Fecha

Se proporcionó una copia de este documento al consumidor. ☐

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CRAVINGS ASSESSMENT

Date: _____ Name: _____ Case No.: _____

URGE-TO-USE SCALE – OPIATES/ALCOHOL

Instructions: The following questions are designed to help you assess an important aspect of your recovery status – the urge to use opiates/alcohol.

DURING THE PAST WEEK

1. How often have you thought about using opiates/alcohol or about how good using opiates/alcohol would make you feel during this period?

☐	Never	0 times during this period of time
☐	Rarely	1 to 2 times during this period of time
☐	Occasionally	3 to 4 times during this period of time
☐	Sometimes	5 to 10 times during this period, or 1 to 2 times per day
☐	Often	11 to 20 times during this period or 2 to 3 times per day
☐	Most of the time	20 to 40 times during this period or 3 to 6 times per day

2. At its most severe point, how strong was your urge to use opiates/alcohol during this period?

- ☐ None at all
- ☐ Slight, a very mild urge
- ☐ Mild urge
- ☐ Moderate urge
- ☐ Strong urge but easily controlled
- ☐ Strong urge and difficult to control
- ☐ Strong urge and would have used opiates/alcohol if available

3. How much time have you spent thinking about opiates/alcohol or about how good using opiates/alcohol would make you feel during this period?

- ☐ None at all
- ☐ Less than 20 minutes
- ☐ 21 to 45 minutes
- ☐ 46 to 90 minutes
- ☐ 90 minutes to 3 hours
- ☐ Between 3 to 6 hours
- ☐ More than 6 hours

4. How difficult would it have been to resist using opiates/alcohol during this period if you had these substances available to you?

- ☐ Not difficult at all
- ☐ Very mildly difficult
- ☐ Mildly difficult
- ☐ Moderately difficult
- ☐ Very difficult
- ☐ Extremely difficult
- ☐ Would not be able to resist

5. Keeping in mind your responses to the previous questions, please rate your overall average urge to use opiates/alcohol during the past week.

- ☐ Never thought about using opiates/alcohol and never had the urge to use opiates/alcohol
- ☐ Rarely thought about using opiates/alcohol and rarely had the urge to use opiates/alcohol
- ☐ Occasionally thought about using opiates/alcohol and occasionally had the urge to use opiates/alcohol
- ☐ Sometimes thought about using opiates/alcohol and sometimes had the urge to use opiates/alcohol
- ☐ Often thought about using opiates/alcohol and often had the urge to use opiates/alcohol
- ☐ Thought about using opiates/alcohol most of the time and had the urge to use opiates/alcohol most of the time
- ☐ Thought about using opiates/alcohol nearly all the time and had the urge to use opiates/alcohol nearly all of the time

APPENDIX G

HEALTHWEST
LABORATORY MONITORING GUIDELINES FOR USE OF PSYCHOTROPIC MEDICATIONS

Mood Stabilizers
Carbamazepine (Carbatrol, Equetro, Tegretol) and Oxcarbazepine (Trileptal)

TESTS	BASELINE	2nd WEEK	1st MONTH	3RD MONTH	6TH MONTH	YEARLY
Pregnancy Test	Every 3 months for women of childbearing age					
CBC (not for Trileptal)	Yes		Yes	If indicated		Yes, or early as indicated
Liver Function Test	Yes		Yes			Yes, or early as indicated
Carbamazepine Level (Tegretol)	1 week		Yes, or early or if meds increase/ decrease			Yes, or early as indicated
Kidney Function Test (BUN and Creatinine)	Yes					If indicated
TSH	Yes					If indicated
Electrolytes, especially with Trileptal (BMP)	Yes		Yes			Yes

Mood Stabilizers
Lithium (Eskalith, Lithobid, and Lithium)

TESTS	BASELINE	WEEK 1	WEEK 2	1ST MONTH	6TH MONTH	ANNUALLY
Pregnancy Test	Every 3 months for women of childbearing age					
Serum Levels		Yes	Yes, if meds increase/ decrease until levels stabilize		Yes	Ye, or early if indicated
Urine Analysis	Yes					If indicated
TSH	Yes		Yes		Yes	Yes, or early if indicated
ECG*	If indicated or if 45 years or older and if pre-existing cardiac disease					If indicated
BUN/Creatinine	Yes		Yes			Yes

Mood Stabilizers

Valproic Acid (Depakene) and Divalproex Sodium (Depakote)

TESTS	BASELINE	2 WEEKS	1 MONTH	3 MONTHS	6 MONTHS	YEARLY	IF SYMPTOMS ARISE
Pregnancy	Every 3 months for women of childbearing age						Yes
CBC with Platelets	Yes	Yes			Yes	Yes	Yes
Liver Function Tests	Yes	Yes				Yes	
Electrolytes (BMP)	Yes						Yes
Drug Levels		Yes, and weekly until stabilized				Yes	Yes
Prothrombin Time							Yes
Androgens							
Amylase							Yes
Bicarb *only for Topamax	Yes		Yes				Yes

Mood Stabilizers

Lamotrigine (Lamictal)

TESTS	BASELINE	IF SYMPTOMS ARISE
Drug Level		Yes (if indicated)
Pregnancy	Every 3 months for women of childbearing age	

*Second Generation Antipsychotic

In addition to Clozapine and Chlorpromazine

TESTS	BASELINE	8 WEEKS OR EARLY AS INDICATED	QUARTERLY	YEARLY	IF SYMPTOMS ARISE
Pregnancy	If indicated				Yes
Weight/BMI	Yes	Yes	Yes	Yes	
Waist Circumference	Yes			Yes	
Blood Pressure	Yes		Yes	Yes	Yes
Fasting Glucose/HbA1C	Yes			Yes	Yes
ECG	If indicated				Yes
Fasting Lipids Panel	Yes			Yes	
Drug Level					If indicated

*Clozapine (Clozaril): Refer to Clozapine/Clozaril Procedures. Use protocol for ANC.

ANTIDEPRESSANTS

A. SNRIs: Venlafaxine (Effexor), Duloxetine (Cymbalta)

	BASELINE	QUARTERLY
BP	Yes	Yes
Hepatic Enzyme (Duloxetine)	If indicated	If indicated

B. MAOIs

	BASELINE	QUARTERLY	YEARLY
Liver Enzymes	Yes		Yearly
BP	Yes		Yearly

C. Tricyclics

	BASELINE	YEARLY
Pregnancy Test	If indicated	
ECG	If indicated	If indicated
Drug Level		If indicated
Liver Function Test		If indicated

D. Serotonin: 2 Antagonist/Reuptake Inhibitors: Nefazodone (Serzone)

	BASELINE	YEARLY
Liver Function Test	Yes	Yes, or earlier if indicated

Medication Assisted Treatment

Vivitrol
(Vivitrol Injection)

TESTS	BASELINE	2nd WEEK	1st MONTH	3RD MONTH	6TH MONTH	YEARLY
Pregnancy Test	Yes And at provider discretion					
Liver Function Test	Yes			Yes	Yes	Yes, every three months throughout treatment
Drug Screen	Yes					To be done prior to each injection.

Campral
(Acamprosate)

TESTS	BASELINE	2nd WEEK	1st MONTH	3RD MONTH	6TH MONTH	YEARLY
Pregnancy Test	Yes And at provider discretion					
Kidney Function Test (BUN/Creatinine)	Yes				Yes	Yes, every six months throughout treatment
Electrolytes	Yes				Yes	Yes, every six months throughout treatment

Revia, Antabuse
(Naltrexone, Disulfiram)

TESTS	BASELINE	2nd WEEK	1st MONTH	3RD MONTH	6TH MONTH	YEARLY
Pregnancy Test	Yes And at provider discretion					
Liver Function Test	Yes			Yes	Yes	Yes, every three months throughout treatment
ECG	Yes if not done in the last 6 months					
Hepatitis Screen	Yes					
HIV	Yes					
Electrolytes	Yes				Yes	Yes, every six months throughout treatment

Suboxone
(Buprenorphine, Naloxone)

TESTS	BASELINE	2nd WEEK	1st MONTH	3RD MONTH	6TH MONTH	YEARLY
Pregnancy Test	Yes And at provider discretion					
Liver Function Test	Yes			Yes	Yes	Yes, every three months throughout treatment
Kidney Function Test (BUN/Creatinine)	Yes					
Electrolytes	Yes					
Hepatitis Screen	Yes					
HIV Screen	Yes					