	Shasta County Health and Human Services Agency Mental Health Plan	
	Medication Instructions and Consent	No. 2015-02
		Issue Date: 2/2024
		Last Revised:7/25/2019
		Page: 1 of 3
		Author: Quality Management

Definitions

Psychotropic medication or psychotropic drugs are those medications administered for the purpose of affecting the central nervous system to treat psychiatric disorders or illnesses. These medications include, but are not limited to, anxiolytic agents, antidepressants, mood stabilizers, antipsychotic medications, anti-Parkinson agents, hypnotics, medications for dementia, and psycho stimulants, and medications used for side effects caused by psychotropic medications.

Policy

It is the policy of the Shasta County Mental Health Plan (MHP) to provide and document informed consent of the beneficiary agreeing to the administration of psychiatric medication. The documentation shall include, but not be limited to: the reasons for taking such medications; reasonable alternative treatments available, if any; the type, range of frequency and amount, method (oral or injection), and duration of taking the medication; probable side effects; possible additional side effects which may occur to beneficiaries taking such medication beyond three (3) months; and, that the consent, once given, may be withdrawn at any time by the beneficiary.

Procedure

"A voluntary patient shall be treated with antipsychotic medications only after such person has been informed of his or her right to accept or refuse such medications and has consented to the administration of such medications. In order to make an informed decision, the patient must be provided with sufficient information by the physician prescribing such medications (in the patient's native language, if possible) which shall include the following:

a) The nature of the patient's mental condition;

b) The reasons for taking such medication, including the likelihood of improving or not improving without such medication, and that consent, once given, may be withdrawn at any time by stating such intention to any member of the treating staff;

c) The reasonable alternative treatments available, if any;

d) The type, range of frequency, and amount (including use of PRN orders), method (oral or injection), and duration of taking the medications;

e) The probable side effects of these drugs known to commonly occur, and any particular side effects likely to occur with the particular patient;

f) The possible additional side effects which may occur to patients taking such medications beyond three months. The patient shall be advised that such side effects may include persistent involuntary movement of the hands and feet, and that these symptoms of

tardive dyskinesia are potentially irreversible and may appear after medications have been discontinued." (CCR Tit.9 § 851)

The prescriber shall ensure that informed consent is provided to the client/parent/legal representative by ensuring a Consent for Medication form is completed in Shasta County's EHR, NetSmart Avatar indicating that the aforementioned information (Sections a-f) has been discussed with the client/parent/legal representative.

- If the client/parent/legal representative refuses to consent or declines to take the medication, the prescriber shall in the progress note indicate that the client/parent/legal representative does not agree to sign the form and/or the client declines to take the medication.
  Note: No Consent for Medication means the client will not receive that medication for treatment; No exceptions.

- The client/parent/legal representative may withdraw their consent to psychotropic medication at any time by stating such intention to the prescriber or nursing staff. The withdrawal of consent shall be noted immediately in the medical record and appropriate medical staff are to be notified as per protocol that the medication consent has been rescinded.

The following steps will be adhered to in completing the Consent for Medication Form to indicate informed consent.

1) For adults 18 and over, the Consent for Medication Form will be completed by the prescriber or staff.

2) For youth 17 and under, the Consent for Medication form will indicate informed consent of the parent/legal representative.

3) For youth 17 and under who are dependents of the court, the Consent for Medication will indicate a legal representative of the court.

4) A copy of the Consent for Medication form (see **Attachment A: Sample Medication Consent**) and a Medication Information Leaflet, for each medication prescribed, will be given to the client/legal representative (see **Attachment B: Sample Medication Information Leaflet).**

5) For youth 17 and under who are dependents of the court, a copy of the Consent for Medication and a Medication Information Leaflet for each medication prescribed, will be given to the caregiver accompanying the youth.

6) A copy of all Consents for Medication will be maintained in the EHR.

7) Laboratory, Abnormal Involuntary Movement Scale and any other appropriate workup shall be ordered by the prescribing provider commensurate with starting an antipsychotic medication.

The informed consent process must be repeated, including Sections A. and B. above, in the following circumstances.

a) The client previously declined the medication but subsequently agrees to accept the medication.

b) The medication has been discontinued and subsequently restarted after an interval of one year or more.

c) The medication consent is over a year old.

d) New information about the medication, such as dosage, side effects, risks, indications, or other significant information is recognized.

*Dosage ranges may be used on the medication consent in the event of frequent dosage changes with a client.

References

Welfare and Institutions Code sections 5213 (b), 5325.1, 5325.3, 5326.2, 5326.3, 5326.5, 5332 (c), 5350, 369.5(a), 739.5(a). Title 9, Section 850-857; Rule 1432.5, Title 22 Section 70707 (b) (6). Common Law Cobbs v. Grant (1972) 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505, Family Code Section 6924(f), Health and Safety Code section 124260(e), and MHSUDS 17-040

Attachments

Attachment A: Sample Medication Consent
Attachment B: Sample Medication Information Leaflet

Authorization

The above policy has been reviewed and is authorized for immediate implementation:

DocuSigned by:
Matthew Wong
88DECF364DFC4EE...

Dr. Wong, MD, Chief of Psychiatry
Shasta County Health and Human Services Agency

01/29/2024 | 2:32 PM PST
Date

DocuSigned by:
Miguel Rodriguez
12357C50B45D437...

Miguel Rodriguez, LCSW, MH Director
Shasta County Health & Human Services Agency

01/26/2024 | 10:47 AM PST
Date

DocuSigned by:
Christy Coleman
9C6EB7A504F94B9...

Christy Coleman, Compliance Officer
Administration, Assistant Director
Health & Human Services Agency

01/29/2024 | 9:03 AM PST
Date

ATTACHMENT A: SAMPLE MEDICATION CONSENT
Date Created: 07/26/2023 at 11:53 AM PDT
Form Name: Consent for Medication
Client's Name: TEST,FORMDEV (999999999)
Client's DOB: 06/05/1990

Shasta County Health and Human Services
Shasta County
Header

Consent for Medication

my medication(s) is/are recommended for me:

Aggression or hostility, Anxiety or constant worrying

Additional Medication Information:

Yes, telephone declined

Draft/Final

Signature of Client:

Signature of Physician/APRN/PA:

Final

Client Sig Date:

07/26/2023

Client Sig Time:

11:53 AM

Electronically Signed by: SCOTT A SOCKWELL Admin on 07/26/2023 at 11:53 AM PDT Author

Cariprazine

pronounced as (kar ip ra zeen)

IMPORTANT WARNING:

Important warning for older adults with dementia:

Studies have shown that older adults with dementia (a brain disorder that affects the ability to remember, think clearly, communicate, and perform daily activities and that may cause changes in mood and personality) who take antipsychotics (medications for mental illness) such as cariprazine have an increased chance of death during treatment. Older adults with dementia may also have a greater chance of having a stroke or mini-stroke during treatment.

Cariprazine is not approved by the Food and Drug Administration (FDA) for the treatment of behavior disorders in older adults with dementia. Talk to the doctor who prescribed this medication if you, a family member, or someone you care for has dementia and is being treated with cariprazine. For more information visit the FDA website: http://www.fda.gov/Drugs [http://www.fda.gov/Drugs] .

Important warning for people with episodes of depression:

A small number of children, teenagers, and young adults (up to 24 years of age) who took antidepressants ('mood elevators') such as cariprazine during clinical studies became suicidal (thinking about harming or killing oneself or planning or trying to do so). Children, teenagers, and young adults who take antidepressants to treat depression or other mental illnesses may be more likely to become suicidal than children, teenagers, and young adults who do not take antidepressants to treat these conditions. However, there are also risks when depression is not treated in children and teenagers. Talk to your child's doctor about these risks and whether your child should take an antidepressant. Cariprazine has not been studied in children younger than 18 years of age.

You should know that your mental health may change in unexpected ways when you take cariprazine or other antidepressants even if you are an adult over 24 years of age. You may become suicidal, especially at the beginning of your treatment and any time that your dose is increased or decreased.

You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: new or worsening depression; thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep or staying asleep; aggressive behavior; irritability; acting without thinking; severe restlessness; and frenzied abnormal excitement. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.

Your healthcare provider will want to see you often while you are taking cariprazine, especially at the beginning of your treatment. Be sure to keep all appointments for office visits with your doctor.

The doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with cariprazine. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also obtain the Medication Guide from the FDA website: http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm.

No matter what your age, before you take an antidepressant, you or your caregiver should talk to your doctor about the risks and benefits of treating your condition with an antidepressant or with other treatments. You should also talk about the risks and benefits of not treating your condition. You should know that having depression or another mental illness greatly increases the risk that you will become suicidal. This risk is higher if you or anyone in your family has or has ever had bipolar disorder (mood that changes from depressed to abnormally excited) or mania (frenzied, abnormally excited mood) or has thought about or attempted suicide. Talk to your doctor about your condition, symptoms, and personal and family medical history. You and your doctor will decide what type of treatment is right for you.

Talk to your doctor about the risks of taking cariprazine.

Why is this medication prescribed?

Cariprazine is used to treat schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions). Cariprazine is also used to treat episodes of depression in people with bipolar I disorder (manic depressive disorder; a disease that causes episodes of mania, episodes of depression and other abnormal moods). It is also used as a short term treatment for episodes of mania or mixed episodes (symptoms of mania and depression that happen together) in people with bipolar I disorder. Cariprazine is also used along with other medications to treat depressive symptoms in adults with major depressive disorder (MDD). Cariprazine is in a class of medications called atypical antipsychotics. It works by changing the activity of certain natural substances in the brain.

How should this medicine be used?

Cariprazine comes as a capsule to take by mouth. It is usually taken once a day with or without food. Take cariprazine at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take cariprazine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor will probably start you on a low dose of cariprazine and gradually increase your dose depending on how well the medication works for you, and the side effects you experience.

Cariprazine may help control your symptoms but will not cure your condition. It may take several weeks or longer before you feel the full benefit of cariprazine. Continue to take cariprazine even if you feel well. Do not stop taking cariprazine without talking to your doctor. Talk to your doctor if you do not feel like you are getting better during your treatment with cariprazine.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking cariprazine,

- tell your doctor and pharmacist if you are allergic to cariprazine, any other medications, or any of the ingredients in cariprazine capsules. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- The following nonprescription or herbal products may interact with cariprazine: St. John's wort. Be sure to let your doctor and pharmacist know that you are taking this medication before you start taking cariprazine. Do not start this medication while taking cariprazine without discussing with your healthcare provider.
- tell your doctor if you or anyone in your family has or has ever had impaired fasting glucose (pre-diabetes) or diabetes. Also, tell your doctor if you have a low number of white blood cells, or if you have ever developed a low number of white blood cells as a side effect of a medication that you took. Tell your doctor if you have or have ever had seizures; a stroke; a ministroke; a heart attack; heart failure; irregular heartbeat; low or high blood pressure; high levels of cholesterol and other fatty substances in the blood; trouble keeping your balance; difficulty swallowing;or heart, liver, or kidney disease. Also tell your doctor if you have severe vomiting, diarrhea or signs of dehydration now, or if you develop these symptoms at any time during your treatment.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy, or if you plan to become pregnant or are breastfeeding. If you become pregnant while taking cariprazine, call your doctor. Cariprazine may cause problems in newborns following delivery if it is taken during the last months of pregnancy.
- you should know that cariprazine may make you drowsy, and may affect your ability to think clearly, make decisions, and react quickly. Do not drive a car or operate machinery during your treatment with cariprazine until you know how this medication affects you.
- you should know that you may experience hyperglycemia (increases in your blood sugar) while you are receiving this medication, even if you do not already have diabetes. If you have schizophrenia, you are more likely to develop diabetes than people who do not have schizophrenia and receiving cariprazine or similar medications may increase this risk. Tell your doctor immediately if you have any of the following symptoms during your treatment: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because

high blood sugar can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include: dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.

- you should know that cariprazine may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. This is more common when you first start taking cariprazine. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- you should know that cariprazine may make it harder for your body to cool down when it gets very hot. Tell your doctor if you plan to do vigorous exercise or be exposed to extreme heat. Be sure to drink plenty of water and call your doctor if you experience any of the following symptoms: feeling very hot, sweating heavily, not sweating even though it is hot, dry mouth, excessive thirst, or decreased urination.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Cariprazine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- extreme tiredness
- restlessness
- anxiety
- agitation
- difficulty falling asleep or staying asleep
- dizziness, feeling unsteady, or having trouble keeping your balance
- increased appetite
- weight gain
- constipation
- indigestion
- nausea
- increased saliva or drooling
- blurred vision

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS section, call your doctor immediately or get emergency medical treatment:

- seizures
- unusual movements of your body or face that you cannot control
- slow movements or shuffling walk
- loss of ability to move
- falling
- fever, sweating, confusion, fast breathing, fast or irregular heartbeat, and severe muscle stiffness
- muscle weakness or aching
- blank facial expression
- difficulty swallowing or breathing
- tightness in the throat
- tongue that sticks out of the mouth
- rash
- itching
- hives
- swelling of the face, throat, tongue, lips, or eyes
- dark or cola-colored urine
- swelling in legs and feet
- decreased urination

Cariprazine may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (http://www.fda.gov/Safety/MedWatch [http://www.fda.gov/Safety/MedWatch]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way

to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (http://goo.gl/c4Rm4p [http://goo.gl/c4Rm4p]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. http://www.upandaway.org [http://www.upandaway.org]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at https://www.poisonhelp.org/help [https://www.poisonhelp.org/help] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- sedation
- feeling lightheaded, dizzy or faint when standing up from a sitting or lying down position

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to cariprazine.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Vraylar ®

Last Revised - 02/15/2023

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