

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 03/23/2021

Completion of this form is voluntary. If informed consent is not given, the medication cannot be administered without a court order unless in an emergency.

This consent is maintained in the client's record and is accessible to authorized users.

Name – Patient / Client (Last, First MI)		ID Number	Living Unit	Date of Birth
Name – Individual Preparing This Form		Name – Staff Contact		Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Progestin (for non-contraceptive use) (systemic)	<ul style="list-style-type: none"> ▪ Depo-Provera intramuscular or subcutaneous injection (Medroxyprogesterone acetate) ▪ Provera oral tablet (medroxyprogesterone acetate) 	Dosage varies by condition treated	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.

Recommended daily total dosage range of manufacturer, as stated in *Physician's Desk Reference* (PDR) or another standard reference.

This medication will be administered Orally Injection Other – Specify:

1. Reason for Use of Psychotropic Medication and Benefits Expected (note if this is 'Off-Label' Use)

Include DSM-5 diagnosis or the diagnostic impression ("working hypothesis.")

2. Alternative mode(s) of treatment other than OR in addition to medications include

Note: Some of these would be applicable only in an inpatient environment.

- | | |
|---|---|
| <input type="checkbox"/> Environment and/or staff changes | <input type="checkbox"/> Rehabilitation treatments/therapy (OT, PT, AT) |
| <input type="checkbox"/> Positive redirection and staff interaction | <input type="checkbox"/> Treatment programs and approaches (habilitation) |
| <input type="checkbox"/> Individual and/or group therapy | <input type="checkbox"/> Use of behavior intervention techniques |

Other Alternatives:

3. Probable consequences of NOT receiving the proposed medication are

Impairment of Work Activities Family Relationships Social Functioning

Possible increase in symptoms leading to potential

- | | |
|--|--|
| <input type="checkbox"/> Use of seclusion or restraint | <input type="checkbox"/> Limits on recreation and leisure activities |
| <input type="checkbox"/> Limits on access to possessions | <input type="checkbox"/> Intervention of law enforcement authorities |
| <input type="checkbox"/> Limits on personal freedoms | <input type="checkbox"/> Risk of harm to self or others |
| <input type="checkbox"/> Limit participation in treatment and activities | |

Other Consequences:

Note: These consequences may vary depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

See Page 2

Client Initial _____ Date _____

4. Possible side effects, warnings, and cautions associated with this medication are listed below. This is not an all-inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text, such as the PDR. As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects in order to enhance care and treatment.

Continued – Possible side effects, warnings, and cautions associated with this medication.

Most Common Side Effects: In females: Common side effects may be changes in vaginal bleeding (increased amounts of menstrual bleeding occurring at regular monthly periods, lighter vaginal bleeding between menstrual periods, heavier vaginal bleeding between regular monthly periods, or stopping of menstrual periods). In males: Common side effects include the inability to achieve or maintain erection, hypogonadism, leg cramps and diminished sperm production. In addition, there may be an increased risk of rare feminization effects such as breast swelling and changes in hair distribution during prolonged treatment. In both males and females: Abdominal pain or cramping; bloating or swelling of ankles or feet; blood pressure increase (mild); dizziness; drowsiness; headache (mild); mood changes; weight gain or loss; nervousness; pain or irritation at place of injection site.

Less Common Side Effects: mental depression; skin rash; swelling of face, ankles, or feet; unexpected or increased flow of breast milk (females); acne; breast pain or tenderness; brown spots on exposed skin, possibly long-lasting; hot flashes; loss or gain of body, facial, or scalp hair; loss of sexual desire or function; trouble in sleeping; anxiety; nausea; joint pain; bone loss; vaginal bacterial infections; urinary tract infections; yeast infections; back pain; symptoms of blood sugar problems (Symptoms of: dry mouth, frequent urination, loss of appetite, or unusual thirst).

Rare Side Effects: Although rare, please contact your doctor as soon as possible if any of the following side effects occur: fast, pounding heartbeat; severe fluid collection in the ankles, feet, or face; bone pain or noticeable fractures; pain during sexual intercourse; hives; severe rash; difficulty breathing; swelling of the lips, tongue, or face; fainting; development of lumps in the breast; yellowing of the eyes or skin; chest pain; excessive sweating; or fever.

Cautions

- **Weight gain**
Contraceptive therapy with medroxyprogesterone commonly results in an average weight gain of 8 pounds after 2 years of treatment.
- **Vaginal bleeding**
Unscheduled bleeding/spotting may occur. Presentation of irregular, non-improving vaginal bleeding following previously regular cycles warrants further evaluation by your doctor. If you notice irregular bleeding or spotting that does not resolve after a few cycles, please contact your doctor.
- **Bone loss**
There is an increased risk of bone loss with the injectable form of medroxyprogesterone, known as Depo-Provera. If you notice any new bone pain, difficulty with movement, or believe you have a fracture, please call your doctor right away. Generally, use of the injectable form of this medication should be limited to a maximum of 2 years. Please inform your doctor if you have taken this medication before.
- **Vision loss**
This is a rare, but serious, complication of therapy with oral and injectable forms of medroxyprogesterone. If you experience a partial or complete loss of vision, double vision, or any other changes in vision, it may be due to a blood clot forming in the eye. Call your doctor right away if this happens to you.
- **Depression**
If you notice new or worsening depression while taking this medication, please call your doctor.
- **Migraines**
Please inform you doctor if you experience migraines before taking this medication. If you experience new or worsening migraines while taking this medication, please call your doctor.

Warning: [Black Box Warning]: Injection risks with bone loss: Women who use injectable medroxyprogesterone acetate may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible. It is unknown if use of injectable medroxyprogesterone acetate during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life. Injectable medroxyprogesterone acetate should be used long-term (e.g., longer than 2 years) only if other methods of birth control are inadequate.

Warning: [Black Box Warning]: Oral tablet cardiovascular, cancer, and other risks: Estrogens with progestins should not be used for the prevention of cardiovascular disease or dementia. The Women's Health Initiative (WHI) estrogen plus progestin substudy reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with daily oral conjugated estrogens (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) relative to placebo. The Women's Health Initiative Memory Study (WHIMS), a substudy of the WHI study, reported increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with daily CE 0.625 mg combined with MPA 2.5mg, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women. In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and MPA and other combinations and dosage forms of estrogens and progestins. Because of these risks, estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

See standard reference text for an all-inclusive list of side effects.

By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather, it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager, or psychologist.
4. I have the right to request a review at any time of my record, pursuant to § 51.30(4)(d) or § 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager, or agency/facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the **anticipated dosage range** without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s), and the probable consequences that may occur if the proposed medication is not given. I have been given adequate time to study the information and find the information to be specific, accurate, and complete.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

SIGNATURES

DATE SIGNED

Client – If Presumed Competent to Consent/Parent of Minor/Guardian (POA-HC)	Relationship to Client <input type="checkbox"/> Self <input type="checkbox"/> Parent <input type="checkbox"/> Guardian (POA-HC)	
Staff Present at Oral Discussion	Title	

Client / Parent of Minor / Guardian (POA-HC) Comments

As parent/guardian (POA-HC) was not available for signature, he/she was verbally informed of the information in this consent.

Verbal Consent

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received <input type="checkbox"/> Yes <input type="checkbox"/> No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received