DEPARTMENT OF HEALTH SERVICES
Division of Care and Treatment Services
F-24277 (05/2024)

STATE OF WISCONSIN
42 CFR483.420(a)(2)
DHS 134.31(3)(o)
DHS 94.03 & 94.09
§§ 51.61(1)(g) & (h)

INFORMED CONSENT FOR MEDICATION

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
Antipsychotic, Anticholinergic/Antimuscarinic	Cobenfy (xanomeline/trospium chloride)	Xanomeline 50 mg/trospium 20 mg orally twice daily for at least 2 days, then xanomeline 100 mg/trospium 20 mg orallly twice daily for at least 5 days, may increase to MAX of xanomeline 125 mg/trospium 30 mg orally twice daily	

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.

☐ Environment and/or staff changes
☐ Positive redirection and staff interaction
☐ Individual and/or group therapy
☐ Rehabilitation treatments/therapy (OT, PT, AT)
☐ Treatment programs and approaches (habilitation)
☐ Use of behavior intervention techniques

Other Alternatives:

Client Initial _____ Date _____

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

☐ Use of seclusion or restraint
☐ Limits on access to possessions
☐ Limits on personal freedoms
☐ Limit participation in treatment and activities
☐ Limits on recreation and leisure activities
☐ Intervention of law enforcement authorities
☐ Risk of harm to self or others

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.

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: The most common side effects include hypertension, abdominal pain, constipation, diarrhea, indigestion, nausea, vomiting.

Less Common Side Effects: Less common side effects include tachycardia, gastrointestinal hypomotility, urinary retention, angioedema.

Rare Side Effects: Rare side effects include tachycardia, increased heart rate and sinus tachycardia. Antimuscarinic agents may decrease gastrointestinal motility, especially in those with gastrointestinal obstructive disorders, ulcerative colitis, intestinal atony or myasthenia gravis. Urinary retention may occur with any dose, but was predominately observed with higher dosage. Urinary retention occurred more commonly in men, geriatric patients, and those with clinically significant bladder outlet obstruction and incomplete bladder emptying. Angioedema has been reported during post marketing surveillance of trospium chloride (including a single dose exposure).

Caution: Tachycardia, increased heart rate and sinus tachycardia. The mean increase in heart rate was 9.8 beats per minute (bpm) in an 8-week dedicated study of 24-hour ambulatory blood pressure monitoring in patients with schizophrenia. Peak heart rate elevation of 13.5 bpm occurred on day 8 with an elevation of 11.4 bpm at the end of week 5. Antimuscarinic agents may decrease gastrointestinal motility, especially in those with gastrointestinal obstructive disorders, ulcerative colitis, intestinal atony, or myasthenia gravis. Urinary retention may occur with any dose, but was predominately observed with higher dosage. Urinary retention occurred more commonly in men, geriatric patients, and those with clinically significant bladder outlet obstruction and incomplete bladder emptying. Angioedema has been reported during post marketing surveillance of trospium chloride (including a single dose exposure).

Warning: Cobenfy should be avoided in patients with gastric retention, history of hypersensitivity to xanomeline and trospium chloride, moderate or severe hepatic impairment (Child-Pugh Class B and C), uncontrolled narrow-angle glaucoma and urinary retention.

Syndrome Note:

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

Client Initial _____ Date _____

Medication: Cobenfy – (xanomeline/trospium chloride)

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 ☐ Self ☐ Parent ☐ 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 ☐ Yes ☐ No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received

Client Initial _____ Date _____