DISTRICT OF COLUMBIA ~ DEPARTMENT OF HEALTH ~ ADAP

Dronabinol capsule (Marinol®) and Dronabinol oral solution (Syndros®)

PRIOR AUTHORIZATION PROGRAM Request Form- Initial Request 12 weeks

CLIENT'S NAME: _____ ADAP ID: _____

CLIENT'S DATE OF BIRTH: _____ ADAP Pharmacy: _____

DC ADAP Policy: Marinol® (dronabinol capsule) is an orally acting cannabinoid and like other cannabinoids has complex central nervous system (CNS) effects, including central sympathomimetic activity. The capsules are available as 2mg, 5mg and 10mg. **Syndros®**(dronabinol oral solution) contains dronabinol 5mg/mL and includes inactive ingredients of 50% (w/w) dehydrated alcohol and polyethylene glycol 400. It is available in a multi-dose, amber 30mL glass bottle.

Marinol® and Syndros® require prior approval for coverage. Allow up to 96 hours for completion of request.

Indication for Use:

Dronabinol capsules and dronabinol oral solution have been approved for use in adults for the treatment of anorexia associated with weight loss in patients with acquired immune deficiency syndrome (AIDS). Both dronabinol capsules and oral solution are also indicated for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

Criteria for use:

Please complete and check all that apply:

1. Medical provider meets qualifications to prescribe dronabinol capsules and oral solution. (Federal, State, Local)

   YES ☐ NO ☐
2. Client has a history of substance abuse or dependence, e.g. cocaine, marijuana, alcohol.

   YES ☐ NO ☐
3. Client has a history of hypersensitivity to alcohol.

   YES ☐ NO ☐
4. Client is currently or has received disulfiram- or metronidazole- containing products within 14 days. YES ☐ NO ☐
5. Client is currently receiving anticholinergic medications, e.g. tricyclic antidepressants, antihistamines.

   YES ☐ NO ☐
6. Client has been educated of the risks associated with using dronabinol with other CNS depressants, e.g., alcohol, benzodiazepines.

   YES ☐ NO ☐
7. Client has been screened for psychiatric conditions, e.g. depression, schizophrenia and if present, will be monitored for new or worsening symptoms during dronabinol treatment.

   YES ☐ NO ☐
8. Client of childbearing potential has signed Dronabinol Informed Consent To Take Dronabinol Form. YES ☐ NO ☐
9. Client is not pregnant and has a negative pregnancy test.

   YES ☐ NO ☐

10. Client has been educated on the appropriate storage, handling and administration of dronabinol capsules or dronabinol oral solution.

    YES ☐ NO ☐

11. Client has been informed of potential benefits and risks associated with dronabinol use.

    YES ☐ NO ☐

12. Client's anticipated start date of dronabinol is_____

13. Client's anticipated duration of treatment is _____ months.

14. Please provide the following information:

    Drug: _____ ☐ capsules ☐ oral solution Initial Dose: _____

Recommended dosage and administration: The recommended dose of dronabinol for treatment of anorexia associated with weight loss in patients with acquired immune deficiency syndrome (AIDS)is shown in the table below. CNS symptoms, e.g. feeling high, dizziness, confusion, somnolence generally resolve within 1 to 3 days with continued dosage if they occur. Dose reduction may be required for severe or persistent CNS symptoms.

Patients should be counseled on appropriate storage, handling, and administration of dronabinol.

Drug	Special Instructions	Initial Dose	Dose Titration*- increase gradually to therapeutic effect if tolerated
Dronabinol capsules - Marinol®	None	➢ 2.5 mg before lunch and 2.5 mg before dinner	➢ 2.5 mg before lunch and 5 mg before dinner ➢ 5 mg before lunch & dinner
Dronabinol oral solution - Syndros®	➢ Always administer directly from the provided calibrated oral dosing syringe to ensure accuracy; ➢ Follow immediately with 6 to 8 ounces of water after the dose	➢ 2.1 mg twice daily- 1 hour before lunch and dinner	➢ 2.1 mg 1 hour before lunch & 4.2 mg 1 hour before dinner ➢ 4.2 mg twice daily- 1 hour before lunch and dinner

***Maximum dose limit = capsules: 20 mg daily in 2 divided doses; oral solution: 16.8 mg daily in 2 divided doses**

Physician's signature: _____ Date: _____

Physician's Name (Print): _____Phone #: _____Fax #: _____

Fax Completed Form to Clinical Pharmacy Associates, Inc.

Fax: 1 (888) 971-7229 Phone: 1 (800) 745-0434 ext. 150 Attention: Prior Approval Program

Approval: YES □ NO □ Date_____ Initials_____Office use only

Reason for denial