## Antiemetic/Antivertigo Agents – dronabinol

### WA.PHAR.35 Antiemetic Antivertigo Agents Dronabinol

#### Medical necessity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dronabinol (MARINOL®)</td>
<td>Dronabinol may be considered medically necessary when:</td>
</tr>
<tr>
<td>Dronabinol (SYNDROS®)</td>
<td>Used for the treatment of ONE of the following:</td>
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<tr>
<td></td>
<td>1. Anorexia associated with weight loss in adults with AIDS</td>
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<tr>
<td></td>
<td>2. Nausea and vomiting associated with chemotherapy in adults</td>
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#### Clinical policy:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Clinical Criteria (Initial Approval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dronabinol (MARINOL®)</td>
<td>1. Anorexia associated with weight loss in adults with AIDS</td>
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<tr>
<td>Dronabinol (SYNDROS®)</td>
<td>a. Defined by ONE of the following:</td>
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<tr>
<td></td>
<td>i. Involuntary weight loss in adults of greater than 10% of pre-illness baseline body weight</td>
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<td>ii. BMI less than 20kg/m² in the absence of concurrent illness or medical condition other than AIDS that may cause weight loss</td>
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<td>b. History of failure, contraindication or intolerance to conventional therapies (e.g. megestrol (Megace®))</td>
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<td>c. Dose limit:</td>
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<td></td>
<td>i. Marinol: 20mg per day</td>
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<td>ii. Syndros: 8.4mg twice daily</td>
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<td>2. Prescribed by or in consultation with an HIV specialist</td>
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</table>

**Approve for 6 months**

### Criteria (Reauthorization)

<table>
<thead>
<tr>
<th>Criteria (Reauthorization)</th>
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<tbody>
<tr>
<td>1. Continued diagnosis of AIDS wasting with continued wasting based on reduction of BMI</td>
</tr>
<tr>
<td>2. Documentation of positive clinical benefit</td>
</tr>
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</table>

**Approve for 6 months**

### Clinical Criteria (Initial Approval)

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<table>
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<tr>
<td>1. Nausea and vomiting associated with chemotherapy in adults</td>
</tr>
<tr>
<td>a. Current diagnosis or cancer or history of cancer diagnosis in last year</td>
</tr>
</tbody>
</table>
b. Currently receiving chemotherapy or history of chemotherapy in the last year

c. History of failure, contraindication or intolerance to conventional therapy (e.g. dexamethasone, ondansetron, aprepitant)

2. Dose limit:
   a. Marinol: 15mg/m² per dose for 4 to 6 doses per day
   b. Syndros: 12.6mg/m² per dose for 4 to 6 doses per day

3. Prescribed by or in consultation with an oncology specialist

Approve for 6 months

Criteria (Reauthorization)

Documentation of positive clinical benefit

Approve for 6 months

References

42. Product Information: Marinol(R), dronabinol. Roxane Laboratories, Columbus, OH, 1999.
49. Product Information: MARINOL(R) oral capsules, dronabinol oral capsules. AbbVie Inc (per FDA), North Chicago, IL, 2017.

Policy: Dronabinol

Last Updated 04/18/2018

60. Kaplan YC, Erol A, & Karadas B: False-positive amphetamine/ecstasy (MDMA/3,4-methylenedioxymethamphetamine) (CEDIA) and ecstasy (MDMA/3,4-methylenedioxymethamphetamine) (DRI) test results with fenofibrate. Ther Drug Monit 2012; 34(5):493-495.


63. Product Information: ZOLOFT(R) tablets, oral concentrated solution, sertraline hydrochloride tablets, oral concentrated solution. Pfizer (per Manufacturer), New York, NY, 2011.


67. Product Information: SEROQUEL(R) oral tablets, quetiapine fumarate oral tablets. AstraZeneca Pharmaceuticals (per FDA), Wilmington, DE, 2011.


74. Product Information: SEROQUEL(R) oral tablets, quetiapine fumarate oral tablets. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2013.