USE OF CHOLINESTERASE INHIBITOR (ANTI-DEMENTIA DRUGS) IN CARE CENTRE SETTINGS

Background

Cholinesterase Inhibitors have been proven to delay or slow mental and functional decline related to dementia in individuals with early or mid-stage dementia. These medications have been used in the community to reduce care needs and avoid institutionalization. It is believed that some individuals can continue to benefit after institutionalization.

To be effective, cholinesterase inhibitors require a source of acetylcholine available to the brain. As Alzheimer Disease progresses, the quantity of acetylcholine in the brain declines. This leaves less acetylcholine available and as a result the effectiveness of cholinesterase inhibitors declines. Little benefit on cognition has been recognized when the Folstein MMSE score is less than ten. FAST scores also indicate resident functional status. A FAST score of 1-6b is indicative of a potential opportunity for use of cholinesterase inhibitors. FAST scores will change with cognitive decline associated with progressive disease. As there comes a time when benefit will no longer be derived, ongoing monitoring of MMSE and FAST scores are necessary.

Funding for these medications for individuals who fit the following guidelines is now available in Calgary Health Region care centre settings under the high cost drug list application process. Drug costs outside of the guidelines will not be supported.

Guideline Summary

Policy and Procedure related to the use of anti-dementia drugs comes under High Cost Drugs List in the Continuing Care Pharmacy & Therapeutics Formulary (HDC – 09).

PROTOCOL 1 - Alzheimer Disease & Functional Status

The guideline indicates that individuals who enter into placement with cholinesterase inhibitors within their drug profile continue on the medications as long as the MMSE score is within 10-26 and the FAST level of >6b (i.e. 6c or higher). Both tools must be completed on admission (or within 2 months prior to admission) to prove potential continued benefit of the drug therapy. The FAST scale is repeated every 6 months and the MMSE every 12 months. Support for the drug therapy will be continued as long as any decline does not exceed 4 points on the MMSE and the FAST level >6b at re-testing. Should an individual develop dementia while in a care centre setting, the same criteria apply. Should the individual enter the care centre on Cholinesterase Inhibitors but not fit the above criteria, the medication will be provided for up to 4 months to allow for a gradual tapering off.

PROTOCOL 2 - Lewy Body Disease with Behaviour Disturbances

The guideline allows for a trial of Cholinesterase Inhibitors in the case of Lewy Body Dementia in the event that the atypical neuroleptics and other options have not been tolerated or have failed to
control the symptoms. Should this drug therapy be considered for a behaviour reason, (including the failure of more traditional anti-psychotic medications) a geriatrician or geriatric psychiatrist referral and assessment is necessary.

**PROTOCOL 3 - Alzheimer Disease with Behaviour Disturbances**

Cholinesterase Inhibitors have shown to have a modifying effect on behaviour disturbances associated with dementia. Should this drug therapy be considered for a behaviour reason, (including the failure of more traditional agents including at least 2 mood stabilizing and 2 of the following anti-psychotics, Risperdal, olanzapine, and quetiapine) a geriatrician or geriatric psychiatrist referral and assessment is necessary. As well, behavioural mapping is required 1-2 weeks prior to the therapy and 1-2 weeks following initiation using a behaviour mapping tool. Should the drug prove effective, the guideline recommends continuing the drug under planned geriatrician or psychogeriatrician review.

**Completing the Functional Assessment Staging (FAST) Instrument**

The FAST scoring tool is a validated instrument used to stage functional status in the presence of dementia. It is useful in staging dementia patients with behavioural disturbances and comparing status over time. The FAST instrument looks at the presence or absence of functional ability in 16 areas. The assessor indicates whether or not the ability is present. If disability is related to a co-morbidity rather than cognitive decline, it is scored as “No” and the reason for the disability is noted.

It has been shown that the use of cholinesterase inhibitor medications is not effective after severe cognitive decline. Therefore, the cut-off for use of anti-dementia medications is a FAST level > 6b (i.e. 6c of higher) Anyone scoring more than 6b, related to cognitive status, should not have cholinesterase inhibitors initiated or should have these drugs tapered off and discontinued. Individuals scoring more than 6b will not be funded through the high-cost drug program. **Urinary incontinence is common, and while a component of the FAST, some discretion will be required in terms of differentiating urinary incontinence on the basis of cognitive loss vs. urinary incontinence on a physical basis such as reduced mobility, stress, urge, etc.**

The FAST instrument is completed within 8 weeks of admission to the continuing care centre (if not done within 3 months prior to admission), when an anti-dementia drug is considered and every 6 months following initiation of the drug therapy. The assessor may need to interview the resident and/or primary caregivers and family members to accurately complete the form. Refer to **Annotated Guidelines for Scoring.**
Annotated Guidelines for Scoring

Stage 1: No objective or subjective functional decrement
   The aged subject’s objective and subjective functional abilities in occupational, social, and other settings remain intact, compared with performance 5 to 10 years previously.

Stage 2: Subjective functional decrement, but no objective evidence of decreased performance in complex occupational or social activities
   The most common age-related functional complaints are forgetting names and location of objects and decreased ability to recall appointments. Subjective decrements are generally not noted by intimates or co-workers, and complex occupational and social functioning is not compromised.

Stage 3: Objective functional decrement of sufficient severity to interfere with complex occupational and social tasks
   This is the stage at which persons may begin to forget important appointments for the first time in their lives. Similarly, a professional person who may have been able to write hundreds of articles or reports over the course of his or her lifetime finds it impossible to finish a single report.
   Functional decrements may also become manifest in complex psychomotor tasks, such as ability to travel to new locations. Persons at this stage have no difficulty with routine tasks such as shopping, handling finances, or traveling to familiar locations. They may stop participating in demanding occupational and social settings, whereupon their deficits may no longer be manifest.

Stage 4: Deficient performance in the complex tasks of daily life
   At this stage, persons have difficulty returning from shopping with the correct items and proper amounts of foodstuffs and other materials. Unless supervised, they have difficulty balancing their checkbooks and may make significant financial errors. Functioning in other complex areas is also compromised.
   A pair of brief case histories illustrates this: One patient scheduled a dinner party and instructed one-half of the guests to arrive on a particular day and the other guests to arrive on the following day. Another patient at this stage ostensibly continued to function as an attorney in partnership with the spouse. Although the patient was able to travel independently to and from the office daily, when queried, neither the names nor details of any cases supposedly being worked on could be recalled. In actuality, the spouse had taken on the patient’s caseload.
   Patients at this stage can still function independently in the community, since they can dress, bathe, choose their own clothing, and travel to familiar locations. However, such functioning is compromised, as in the case of the patient at this stage who resided alone, continued to pay rent personally, but, when queried, underestimated the amount of the rent by 50 percent. The same patient incorrectly described the residence as a hotel, when it was actually an apartment house.

Stage 5: Deficient performance in such basic tasks of daily life as choosing proper clothing
   Patients can no longer function independently. The caregiver must assist not only in managing financial affairs and in shopping, but also must assist the patient in choosing the proper clothing for the season and the occasion. The patient will frequently wear obviously incongruous clothing combinations unless the caregiver intervenes. Indeed, this deficit in choosing proper clothing is virtually pathognomonic of this stage. Less characteristically, some patients begin to forget to bathe regularly unless reminded. Sometimes coaxing as well as reminding to bathe is necessary.

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1 Adapted from Reisberg, B., Dementia: A systematic approach to identifying reversible causes, Geriatrics 41:430–446, 1986.
Annotated Guidelines for Scoring (continued)

Patients at this stage are still capable of putting on their clothing properly, once it has been selected for them. They are also capable of bathing themselves and even of adjusting the bathwater properly when washing, although, as mentioned, they may have been cajoled or reminded to bathe.

Another functional deficit that frequently becomes manifest over the course of this stage is difficulty driving an automobile. The patient may inappropriately speed up or slow down the vehicle, mistakenly go through a stop light, or even collide with another vehicle for the first time in many years. Frequently, the patient is sufficiently alarmed by these deficits as to voluntarily discontinue driving. Occasionally coercion from the spouse or other caregiver is necessary.

Stage 6: Decreased ability to dress, bathe, and toilet independently

In uncomplicated Alzheimer's disease (AD), these three functional deficits usually proceed in sequence with the evolution of the illness. Five distinct, sequential functional substages can be identified that allow the physician and caregiver to anticipate the course of the illness. It should be noted that distinctions between these substages may be less marked than those between the major functional stages. Hence, stages 6a and 6b may be evident simultaneously, or in uncomplicated AD, the progressive functional-deficit substages may not occur in sequence. For example, stage 6b may precede 6a.

Substage 6(a): Decreased ability to put on clothing properly. Initially, many patients put their daytime clothing on over their nightclothes. Other patients will, for the first time in their adult lives, experience difficulty tying shoelaces or putting shoes on the proper feet. As the illness advances, increasing assistance from caregivers is needed to help the patients clothe themselves properly.

Substage 6(b): Decreased ability to bathe independently. Ability to properly adjust the bathwater, enter and exit the bath, wash properly, and completely dry oneself declines. As noted above, fear or resistance sometimes precedes actual deficits in bathing.

Substage 6(c): Decreased ability to perform mechanics of toileting independently. Patients at this stage begin to forget to flush the toilet. They may also begin to forget to wipe themselves when toileting, and may develop difficulty in pulling up their underclothing or trousers. The caregiver begins to assist the patient in the mechanics of toileting.

Substage 6(d): Urinary incontinence. Occasionally, this occurs virtually simultaneously with stage 6c, but more frequently there is a discernible interval of a few to several months between these stages. The urinary incontinence occurs at this stage in the absence of infection or other genitourinary tract pathology. It appears to be entirely the result of decreased cognitive capacity to respond to urinary urgency with appropriate toileting behavior.

Substage 6(e): Fecal incontinence. Fecal and urinary incontinence may occur simultaneously or even at the same time that difficulties with the mechanics of toileting become evident. More frequently, this substage is temporally discrete. The mechanism appears to be identical to that of urinary incontinence, i.e., decreased cognitive capacity.

Stage 7: Loss of speech, locomotion, and consciousness

This is the final stage of AD. Although some Alzheimer's patients succumb earlier in the course of the illness to social hazards (e.g., vehicular accidents, assaults, becoming hopelessly lost, or infections for which persons with decreased cognitive capacity have an increased susceptibility), the majority of AD patients survive until some point in the seventh stage. Again, a number of substages afford the clinician and family some predictive capability.

Substage 7(a): Vocabulary becomes limited to fewer than a half-dozen words. Deficits in vocabulary and speech abilities increase with progression of AD. Reticence and a paucity of speech are frequently noted in the fourth and fifth GDS stages. In the sixth stage, the ability to speak in complete sentences is gradually lost. After
Annotated Guidelines for Scoring (continued)

the development of incontinence, speech becomes even more circumscribed to single words or short phrases, and spoken vocabulary becomes limited to only a few words.

Substage 7(b): Intelligent vocabulary becomes limited to a single word. The final spoken word for an AD patient varies. For some patients, the spoken vocabulary becomes limited to the single word “yes.” For other patients the final spoken word is “no.” For one patient, the final word was “okay,” which was repeated in response to all verbalization-provoking phenomena, including need to toilet, express anxiety, and express either the affirmative or the negative.

As the illness progresses, the ability to speak even this final single word is lost. However, months afterward, the patient may suddenly articulate the seemingly forgotten final word, only to return to a state of obliviousness with respect to intelligible speech. After the intelligible speech is lost, vocalizations become limited to grunts and screams.

Substage 7(c): Loss of ambulatory ability. Neuropathologic studies indicate that the motor cortex is spared except in the most severe (late) stages of AD. Perhaps this late cortical deterioration accounts for the loss of ambulatory ability at this late point in the evolution of the disease. It should be noted, however, that lesser forms of ambulatory disturbance are not uncommon at earlier stages. These less severe locomotor disturbances may be the result of decreased cognitive capacities, and resultant psychomotor changes, rather than destruction of the motor cortex per se. For example, inappropriate gait speed (the patient either walks too quickly or too slowly) is not infrequently noted in the earlier stages of the disease. In the sixth stage, the patient may begin to ambulate more deliberately or to take smaller steps. Assistance in walking up and down staircases is generally required prior to the loss of all ambulatory ability.

The onset of ambulatory loss during Stage 7 is somewhat varied. Some patients simply take progressively smaller and slower steps. Others begin to tilt forward, backward, or laterally when ambulating. Twisted gait have also been noted. After ambulatory abilities are lost, other voluntary motoric abilities become compromised.

Substage 7(d): Loss of ability to sit. After AD patients have lost the ability to ambulate without—and subsequently even with—assistance, they are still capable of sitting in a chair unassisted. After ambulatory ability is lost, the ability to sit up unassisted is lost. At this point, the patients are still capable of smiling, chewing, grunting, crying out, and grasping.

Substage 7(e): Loss of ability to smile. At this stage, AD survivors can generally still move their eyes and may appear to show deliberate ocular movements in response to stimuli; however, they no longer recognize familiar persons or objects. Grasp reflexive ability is also preserved, as is the ability to swallow and even to chew in many patients. Also, patients at this stage continue to cry out in response to stimuli.

Substage 7(f): Loss of ability to hold up head. The few AD patients who survive to this point may need to be fed with a pipette, in part because of their decreased capacity to recognize food. They may still make noises, but these vocalizations are not readily associated with exogenous stimuli.
COMPLETING THE MINI-MENTAL STATE EXAMINATION (MMSE)

The Mini-mental State Examination is completed at admission (or within 2 months of admission) and re-administered annually. Cholinesterase inhibitors continue to be effective as long as the MMSE score is within 10-26.

**Scoring Process Guideline**

**Orientation**

1. Ask for the date. Then ask specifically for parts omitted (e.g. Can you also tell me what season it is?) One point for each correct answer.
2. Ask in turn: “Can you tell me the name of this facility, town, country, etc?” One point for each correct answer.

**Registration**

Ask the resident if you may test his or her memory. Then say the names of three unrelated objects, clearly and slowly, allowing about one second for each. After you have said all three, ask him or her to repeat them. This first repetition determines his or her score (0-3) but keeping saying them until he or she can repeat all three, up to 6 trials. If he or she does not eventually learn all three, recall cannot be meaningfully tested.

**Attention and Calculation**

Ask the patient to begin with 100 and count backwards by 7. Stop after five subtractions (93, 86, 79, 72, 65). Score the total number of correct answers. If the patient cannot or will not perform this task, ask him or her to spell the word “world” backward. The score is the number of letters in correct order.

**Recall**

Ask the resident if he or she can recall the three words you asked him or her to remember. Score one point for each remembered word.

**Language**

1. Naming: Show the resident a wrist watch and ask him or her what it is. Repeat this with a pencil. Score one point for each item correctly named.
2. Repetition: Ask the resident to repeat the sentence after you. Allow only one trial. If repeated correctly, score 1 point.
3. Three-stage command: Give the resident a piece of plain blank paper and repeat the command. Score 1 point for each part of the command correctly executed.
Individual identified as having early or mid-stage dementia with functional deterioration

Physician wishes to consider cholinesterase inhibitor

FAST and MMSE completed

Criteria for cholinesterase inhibitor met?

Application made for High Cost Drug & therapy initiated

FAST repeated at 6 months & MMSE repeated at 12 months

Continues to meet criteria for cholinesterase inhibitor therapy?

Treatment is NOT initiated?

Yes

No

Treatment is NOT continued?

Yes

No

Use of Cholinesterase Inhibitor in Care Centre Settings - Functional Deterioration

September 2003
Use of Cholinesterase Inhibitor in Care Centre Settings - Behavioural Disturbances

September 2003
Individual identified as having Lewy Bodies dementia with behaviour disturbances-other options have proven unsuccessful or inappropriate

Physician wishes to consider cholinesterase inhibitor

Consult made to geriatrician or geriatric psychiatry to follow

24 hour Behaviour mapping for 2 weeks

Consultant recommends cholinesterase inhibitor?

Yes

Application through High Cost Drug program made & therapy initiated

24 hour Behaviour mapping for 2 weeks

Drug Therapy determined to have a positive effect?

No

Treatment is NOT continued

Yes

Drug therapy is continued with a planned review by geriatrician or geriatric psychiatrist

Use of Cholinesterase Inhibitor in Care Centre Settings - Lewy Bodies Dementia

September 2003
FUNCTIONAL ASSESSMENT STAGING (FAST)¹
(See reverse for scoring guideline)

RESIDENT NAME: ___________________ DATE OF BIRTH (Y/M/D): ___________________

FACILITY: ___________________

INFORMANT NAME: ___________________ RELATIONSHIP TO PATIENT: ________________
(if applicable) (if applicable)

1. No difficulties, either subjectively or objectively

2. Complains of forgetting location of objects; subjective work difficulties (i.e. Subjective functional decrement but no objective evidence of decreased performance in complex occupational and social tasks).

3. Decreased job functioning evident to co-workers; difficulty in traveling to new locations (i.e. Objective functional decrement of sufficient severity to interfere with complex occupational and social tasks).

4. Decreased ability to perform complex tasks (e.g. planning dinner for guests; handling finances; marketing) (i.e. Deficient performance in the complex tasks of daily life).

5. Requires assistance in choosing proper clothing (i.e. Deficient performance in such basic tasks of daily life as choosing proper clothing).

6. Decreased ability to dress, bathe, and toilet independently
   (a) Difficulty putting clothing on properly.
   (b) Unable to bathe properly; may develop fear of bathing.
   (c) Inability to handle mechanics of toileting (i.e. forgets to flush, doesn’t wipe properly).
   (d) Urinary incontinence².
   (e) Fecal incontinence².

7. Loss of speech, locomotion, and consciousness
   (a) Ability to speak limited (1 to 5 words a day).
   (b) All intelligible vocabulary lost.
   (c) Non ambulatory.
   (d) Unable to sit up independently.
   (e) Unable to smile.
   (f) Unable to hold head up.

COMMENTS:

____________________________________
____________________________________
____________________________________

________________________
________________________
________________________
________________________

COMPLETED BY (PRINT NAME): DESIGNATION: SIGNATURE: DATE (Y/M/D):

Note: Completed form to be filed on health record

² Cross Reference: HCD Funding Request Form and protocol (HCD-09)
³ Not always related to cognition in nursing home environment. Use with discretion
### Mini-Mental State Examination (MMSE)

<table>
<thead>
<tr>
<th>Scoring</th>
<th>Resident</th>
</tr>
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<tbody>
<tr>
<td><strong>Orientation</strong></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>What is the (year), (season), (date), (day), (month)?</td>
</tr>
<tr>
<td>5</td>
<td>Where are we (province), (country), (town), (facility), (floor)?</td>
</tr>
<tr>
<td><strong>Registration</strong></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Name 3 objects: 1 second to say each. Then ask the client all 3 after you have said them. Give 1 point for each correct answer. Then repeat them until all 3 are learned. Count trials and record. TRIALS ________</td>
</tr>
<tr>
<td><strong>Attention &amp; Calculation</strong></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Serial 7’s. 1 point for each correct. Stop after 5 answers. Alternatively, spell “world” backward.</td>
</tr>
<tr>
<td><strong>Recall</strong></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Ask for the 3 objects repeated above. Give 1 point for each correct.</td>
</tr>
<tr>
<td><strong>Language</strong></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Name a pencil, and watch (2 points). Repeat the following, “No ifs, ands, or buts” (1 point).</td>
</tr>
<tr>
<td>3</td>
<td>Follow a 3-stage command: “Take a paper in your right hand, fold it in half, and put it on the floor”</td>
</tr>
<tr>
<td>1</td>
<td>Read and obey the following: “Close your eyes.”</td>
</tr>
<tr>
<td>1</td>
<td>Write a sentence.</td>
</tr>
<tr>
<td>1</td>
<td>Copy a design.</td>
</tr>
</tbody>
</table>

**TOTAL SCORE**

Assess and Mark Level of Consciousness along the following continuum:

<table>
<thead>
<tr>
<th>Alert</th>
<th>Drowsy</th>
<th>Stupor</th>
<th>Coma</th>
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</thead>
</table>
References


