



Alzheimer's Drug Therapy Initiative

CLINICIAN INFORMATION PACKAGE

OCTOBER 2007

TABLE OF CONTENTS

SECTION 1:	Clinician Outline
SECTION 2:	Criteria for Coverage
SECTION 3:	Algorithms A. for initial coverage of cholinesterase inhibitors B. for continuation of coverage (6-month assessment)
SECTION 4:	Reference Guide to Prescribing Cholinesterase Inhibitors
SECTION 5:	Diagnostic Criteria for Dementias
SECTION 6:	Frequently Asked Questions for Clinicians
SECTION 7:	Special Authority Forms (pads included with package) <ul style="list-style-type: none">• Reference Guide to Completing Special Authority Forms• Initial Coverage – including Standard Mini-Mental State Examination (SMMSE) and Global Deterioration Scale (GDS) with 2-page patient handout (invitation to learn more about the Centre on Aging Study and information sheet)• Renewal/Switching
SECTION 8:	Physician Comments

OTHER MATERIALS INCLUDED WITH THIS PACKAGE:

The Missing Piece for Physicians, including tear-off contact sheet for patients.

*ADDITIONAL CLINICAL MATERIALS WILL BE PROVIDED ON THE ADTI WEBSITE
AT WWW.HEALTH.GOV.BC.CA/PHARME/ADTI/.*



Alzheimer's Drug Therapy Initiative

CLINICIAN OUTLINE

Effective October 22, 2007, through the Alzheimer's Drug Therapy Initiative (ADTI), PharmaCare will begin to provide coverage of the cholinesterase inhibitors donepezil (Aricept[®]), galantamine (Reminyl[®]) and rivastigmine (Exelon[®]) for eligible individuals diagnosed with mild to moderate Alzheimer's disease, including patients with Alzheimer's disease with a vascular component or Parkinsonian features.

In some studies, cholinesterase inhibitors have been shown to benefit cognition, functional abilities and behaviour, either stabilizing or improving the course of the disease over time in some patients. Cholinesterase inhibitors are part of the overall management of dementia patients which includes making an accurate diagnosis, monitoring cognition and function and supporting caregivers to allow the patient to remain safely at home for as long as possible with community resources.

Patients need to be assessed at onset of therapy and every 6 months thereafter to confirm their ongoing eligibility for PharmaCare coverage of cholinesterase inhibitors. Coverage is subject to the patient's plan, annual deductible and family maximum. For the duration of the ADTI, coverage will be continued for as long as the medication is tolerated and seen to be effective. Once a patient moves into the category of severe dementia, or is classified as a non-responder, coverage will be discontinued.

The process for coverage is summarized below and in the attached algorithm. This information is also available on the ADTI website at www.health.gov.bc.ca/pharme/.

1. Familiarize yourself with the attached educational information on Managing Cognitive Impairment in the Elderly (GPAC Guidelines)
2. Determine if there is a diagnosis of Alzheimer's disease
3. Review eligibility criteria (Standardized Mini-Mental State Examination (SMMSE) ≥ 10 to ≤ 26 , Global Deterioration Scale (GDS) ≥ 4 to ≤ 6)
4. Review the contraindications/side effects/drug interactions
5. Confirm that patient has the ability or support necessary to properly take the medication
6. Provide patient and caregiver with brochure and handout (see attached)
7. Submit a Special Authority form for initial coverage
8. Begin the cholinesterase inhibitor (see dosing/titration guidelines on the Special Authority form)
9. At 1-3 months, evaluate for tolerability (common side effects - nausea, vomiting, diarrhea, sleep disturbance)
10. Evaluate cognition, function and behaviour every 6 months to determine effectiveness of medication using SMMSE, GDS, and overall patient assessment rating
11. Submit Special Authority Form for Renewal/Switching Cholinesterase Inhibitors with results of the 6-month assessment. Coverage for eligible patients will be extended for 6 months at a time
12. Consider discontinuing or switching medication if there is poor tolerability or the patient is not responding. Patients are permitted to try all three of the eligible cholinesterase inhibitors. Please use the Special Authority Request for Renewal/Switching Cholinesterase Inhibitors.
13. Submit any questions regarding Special Authority approval in writing to the Special Authority fax number: 1-800-609-4884.

As part of the ADTI, certain individuals may be enrolled in a peer-reviewed research study to determine the group most likely to benefit from treatment with cholinesterase inhibitors. You will be contacted again soon about your interest in participating in this worthwhile research initiative.

It is hoped that the ADTI will be a helpful addition to the management of individuals in the mild to moderate stages of Alzheimer's disease.



Alzheimer's Drug Therapy Initiative

CRITERIA FOR COVERAGE

DONEPEZIL (ARICEPT®), GALANTAMINE (REMINYL®) AND RIVASTIGMINE (EXELON®)

For coverage, diagnosis must be Alzheimer's disease, Alzheimer's disease with a vascular component, Alzheimer's disease with Parkinsonian features (Lewy bodies) or mixed dementia with predominant Alzheimer's disease.

Initiation of coverage in a cholinesterase inhibitor-naïve patient:

Coverage will be provided for an initial 6-month period, when the following criteria are met:

- ▶ a Standardized Mini Mental State Examination (SMMSE) score of ≥ 10 to ≤ 26 , **AND**
- ▶ a Global Deterioration Scale (GDS) stage of 4, 5 or 6.

Note: Check for tolerability in naïve patients within the first 1 - 3 months.

Continuation of coverage for 6-month periods:

Coverage is continued for patients in 6-month increments when:

- ▶ the information provided indicates that the patient remains in the mild to moderate stage of Alzheimer's disease (if repeat SMMSE testing at 6-month intervals results in scores of ≥ 10 **AND**
- ▶ a GDS stage of 4, 5 or 6) **AND**
- ▶ there is demonstrated stabilization or improvement during the previous six months of therapy.

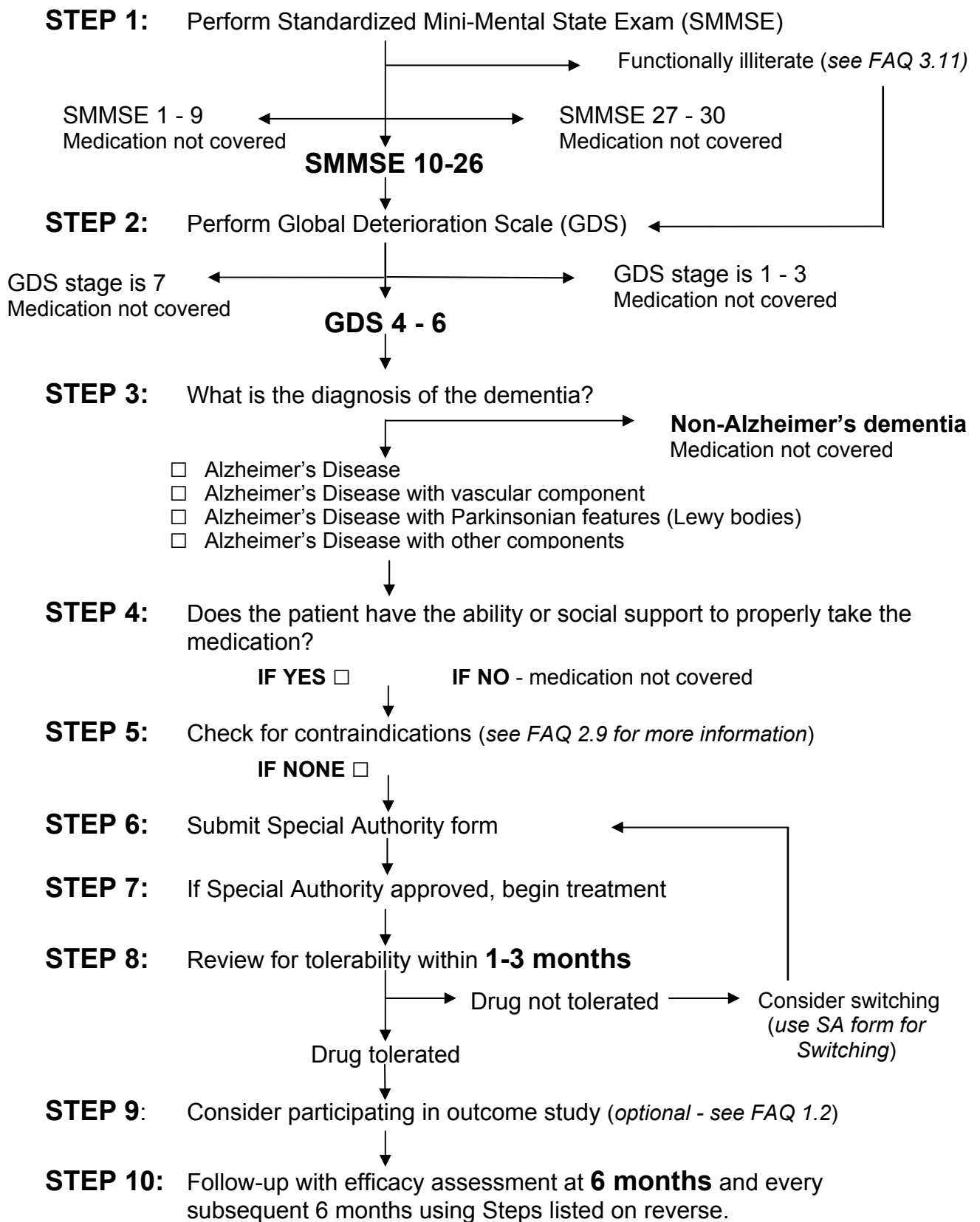
Coverage when switching for lack of efficacy to another cholinesterase inhibitor

Coverage of another cholinesterase inhibitor is provided for an initial 6 months if:

- ▶ the clinician documents the reason for discontinuing the previous cholinesterase inhibitor on the Special Authority Renewal/Switching Form.

Note: Coverage of another cholinesterase inhibitor is provided in the same manner as the previous one (check for tolerability within the first 1 - 3 months, coverage to be renewed in 6-month increments if criteria continue to be met).

ALGORITHM FOR INITIAL COVERAGE OF CHOLINESTERASE INHIBITORS FOR MILD TO MODERATE ALZHEIMER'S DISEASE



ALGORITHM FOR 6-MONTH ASSESSMENT AND CRITERIA FOR CONTINUATION/SWITCHING OF CHOLINESTERASE INHIBITORS FOR MILD TO MODERATE ALZHEIMER'S DISEASE

PharmaCare coverage is continued for patients in 6-month increments when they meet the mandatory requirements as follows:

- individual remains in the mild to moderate stages of Alzheimer's disease (SMMSE ≥ 10 , GDS ≥ 4 to ≤ 6);
- there is stabilization or improvement during the previous 6-month's therapy (review patient's cognitive, functional and behavioural symptoms).

STEP 1	LAST 6-MONTH SMMSE SCORE:	CURRENT SMMSE SCORE:	DIFFERENCE:	<input type="checkbox"/> UNABLE TO COMPLETE SMMSE BECAUSE OF FUNCTIONAL ILLITERACY	GDS STAGE:
STEP 2	ASSESS THE CHANGE IN ABILITY OVER THE LAST 6 MONTHS COGNITION A. MEMORY, REASONING AND PERCEPTION (E.G. NAMES, TASKS, SMMSE) _____ (+1 IMPROVED, 0 NO CHANGE, -1 WORSE) FUNCTION B. INSTRUMENTS OF DAILY LIVING (E.G. TELEPHONE, SHOPPING, MEAL PREPARATION) _____ (+1 IMPROVED, 0 NO CHANGE, -1 WORSE) C. BASIC ACTIVITIES OF DAILY LIVING (E.G. BATHING, DRESSING, HYGIENE, TOILETING) _____ (+1 IMPROVED, 0 NO CHANGE, -1 WORSE) BEHAVIOUR D. NEUROPSYCHIATRIC SYMPTOMS (E.G. AGITATION, DELUSIONS, HALLUCINATION, APATHY) _____ (+1 IMPROVED, 0 NO CHANGE, -1 WORSE) <p style="text-align: center;">TOTAL SCORE (A+B+C+D) _____</p>				
STEP 3	TOTAL SCORE		OVERALL PATIENT ASSESSMENT RATING		RECOMMENDATION
	+4	→ CLINICAL JUDGMENT →	<input type="checkbox"/> VERY MUCH IMPROVED	POSITIVE RESPONDER	CONTINUE TREATMENT; RE-EVALUATE PATIENT EVERY 6 MONTHS
	+3 OR +2		<input type="checkbox"/> MUCH IMPROVED		
	+1		<input type="checkbox"/> MINIMALLY IMPROVED		
	0		<input type="checkbox"/> NO CHANGE	INDETERMINATE RESPONDER	CONTINUE TREATMENT; RE-EVALUATE PATIENT EVERY 6 MONTHS (CONSIDER SWITCHING CHOLINESTERASE INHIBITOR)
	-1		<input type="checkbox"/> MINIMALLY WORSE		
	-2 OR -3		<input type="checkbox"/> MUCH WORSE	NON-RESPONDER	STOP TREATMENT OF CURRENT CHOLINESTERASE INHIBITOR (CONSIDER SWITCHING CHOLINESTERASE INHIBITOR)
	-4		<input type="checkbox"/> VERY MUCH WORSE		
ELIGIBILITY CRITERIA: DIAGNOSIS OF ALZHEIMER'S DISEASE WITH SMMSE ≥ 10 , GDS ≥ 4 to ≤ 6 , OVERALL PATIENT ASSESSMENT RATING OF 'POSITIVE RESPONDER' OR 'INDETERMINATE RESPONDER.'					

REFERENCE GUIDE TO PRESCRIBING CHOLINESTERASE INHIBITORS

	STARTING DOSE	TITRATION AS TOLERATED	EFFECTIVE RANGE	MAXIMUM DAILY DOSE
<input type="checkbox"/> DONEPEZIL	5 mg daily (2.5 if frail) for 4 to 6 weeks	increase by 5 mg	5 to 10 mg daily	10 mg
<input type="checkbox"/> GALANTAMINE	8 mg ER daily for 4 to 6 weeks	increase by 8 mg	16 to 24 mg daily	24 mg
<input type="checkbox"/> RIVASTIGMINE (divided dose)	1.5 mg twice daily for 2 to 4 weeks	increase by 1.5 to 3 mg twice daily	6 to 12 mg daily	12 mg (6 mg twice daily)

RELATIVE CONTRAINDICATIONS

- severe hepatic or renal disease
- significant bradycardia or AV block
- significant bronchospastic disease
- obstructive urinary disease
- active peptic ulcer disease
- seizure disorder

SIDE EFFECTS

- nausea, vomiting, diarrhea
- anorexia with weight loss
- sleep disturbances (donepezil)
- muscle/leg cramps
- syncope, dizziness

GUIDELINES FOR SWITCHING

1. Poor tolerability/side effects
 - not amenable to dosage reduction
 - or slowing titration
2. Lack of efficacy with first drug trial

CURRENT DRUG TO BE DISCONTINUED DUE TO POOR TOLERABILITY

STOP	DONEPEZIL	GALANTAMINE	RIVASTIGMINE
WAIT	5-7 days	2 days	2 days
START	galantamine or rivastigmine	donepezil or rivastigmine	galantamine or donepezil
Dose/titration of new drug	AS FOR NEW START (see above)		

CURRENT DRUG TO BE TAPERED OFF DUE TO LACK OF EFFICACY (mg daily)

	Current Dose	End of Week 1	End of Week 2	Maximum Dose**
Donepezil	10	5	0	n/a
	5	2.5		
	2.5	0		
Galantamine	24	16	0	n/a
	16	8		
	8	0		
Rivastigmine (>1.5mg daily, split into twice daily dosing if possible)	12	6	0	n/a
	9	4.5		
	6	3		
	3	1.5		

NEW DRUG TO BE ADDED WHILE CURRENT DRUG TAPERED (mg daily)

	Current Dose	End of Week 1	End of Week 2	Maximum Dose**
Donepezil OR	-	5 (2.5 if frail)	5	10
Galantamine OR	-	8	16	24
Rivastigmine	-	1.5 to 3 twice daily	6 to 12	12 (6 twice daily)

**Titrate to maximum dose if tolerated and clinically indicated.

PharmaCare note: Cholinesterase inhibitors are currently available by Special Authority for the treatment of mild to moderate Alzheimer's disease only. PharmaCare will NOT be providing coverage of these medications for other types of dementia unrelated to Alzheimer's disease.

For reference purposes only, current diagnostic criteria for other types of dementia are presented below. Note that if the dementia etiology is mixed (e.g. Alzheimer's disease with comorbid cerebrovascular disease or Alzheimer's disease mixed with Lewy body pathology), patients may be eligible for coverage as long as the predominant etiology is Alzheimer's disease.

DIAGNOSTIC CRITERIA FOR DEMENTIAS

DSM-IV CRITERIA FOR ALZHEIMER'S DISEASE

Memory deficit that can be demonstrated objectively on cognitive testing.

At least one other cognitive deficit such as aphasia (abnormal speech), executive function impairment (difficulty with planning, judgment, mental flexibility, abstraction, problem-solving, etc), agnosia (impaired recognition of people or objects), or apraxia (impaired performance of learned motor skills).

Together, these cognitive deficits must result in impairment in performance of daily activities.

The course is characterized by gradual onset and continuing cognitive decline.

These deficits must represent a decline from a previous higher level of functioning.

There must not be any other neurological disease that accounts for them.

DIAGNOSTIC CRITERIA FOR OTHER TYPES OF DEMENTIA

NOT INCLUDED IN THE ALZHEIMER'S DRUG THERAPY INITIATIVE:

NINDS-AIREN CRITERIA FOR VASCULAR DEMENTIA

Dementia defined by cognitive decline from a previously higher level of functioning manifested by impairment of memory and of impairment in at least one other cognitive domain. Deficits should be severe enough to interfere with activities of daily living not due to the physical effects of stroke alone.

Cerebrovascular disease defined by the presence of focal signs on neurologic exam consistent with stroke (with or without history of stroke) AND evidence of relevant CVD by brain imaging (CT or MRI).

A relationship between the above two disorders manifested or inferred by the presence of one or more of the following: (a) onset of dementia within 3 months following a recognized stroke; (b) abrupt deterioration in cognitive functions; or (c) fluctuating, stepwise progression of cognitive deficits.

Clinical features consistent with the diagnosis of probably vascular dementia include:

- (a) early presence of gait disturbance;
- (b) history of unsteadiness and frequent, unprovoked falls;
- (c) early urinary frequency, urgency, and other urinary symptoms not explained by urologic disease;
- (d) pseudobulbar palsy;
- (e) personality and mood changes, abulia, depression, emotional incontinence, or other subcortical deficits including psychomotor retardation and abnormal executive functions.

Editorial note: If a dementia has gradual onset and progression reminiscent of Alzheimer's disease but there is imaging evidence of ischemic lesions and perhaps some abnormalities on neurological examination, the diagnosis is most likely to be (predominant) Alzheimer's disease with comorbid cerebrovascular disease rather than pure vascular dementia.

LUND-MANCHESTER CRITERIA FOR FRONTOTEMPORAL DEMENTIA

The Lund-Manchester diagnostic criteria for frontotemporal dementia require all of the following core components to be present:

1. insidious onset and gradual progression
2. early decline in social interpersonal conduct
3. early impairment in regulation of personal conduct
4. early emotional blunting
5. early loss of insight

Supportive diagnostic features include:

- A. Behavioural disorder
 - decline in personal hygiene and grooming

- mental rigidity and inflexibility
 - distractibility and impersistence
 - hyperorality and dietary change
 - utilization behavior
- B. Speech and language: altered speech output (spontaneity and economy of speech, pressure of speech), stereotypy of speech, echolalia, perseveration, mutism
- C. Physical signs: primitive reflexes, incontinence, akinesia, rigidity, tremor, low/labile blood pressure
- D. Investigations:
- neuropsychology: impaired frontal lobe tests; no amnesia or perceptual deficits
 - EEG: normal on conventional EEG despite clinically-evident dementia
 - brain imaging: predominant frontal and/or anterior temporal abnormality

Editorial note: Most commonly frontotemporal dementia has its onset in middle years, usually presenting with behavioural/personality/conduct issues. Memory is often only minimally affected in early disease.

INTERNATIONAL CONSENSUS CONSORTIUM CRITERIA FOR DEMENTIA WITH LEWY BODIES - McKEITH ET AL, 1996

1. Progressive cognitive decline of sufficient magnitude to interfere with normal social or occupational function. Prominent or persistent memory impairment may not necessarily occur in the early stages but is usually evident with progression. Deficits on tests of attention and frontal-subcortical skills and visuospatial ability may be especially prominent.
2. Two of the following are required for a diagnosis of probable Dementia with Lewy bodies:
 - fluctuating cognition with pronounced variations in attention and alertness
 - recurrent visual hallucinations which are typically well-formed and detailed
 - spontaneous motor features of Parkinsonism
3. Features supportive of the diagnosis are:
 - repeated falls
 - syncope or transient loss of consciousness
 - neuroleptic sensitivity
 - systematized delusions
 - hallucinations in other modalities

Editorial note: In neuropathology studies, Dementia with Lewy bodies and Alzheimer's disease pathology commonly coexist resulting in a spectrum of clinical expression ranging from pure Alzheimer's disease to pure Dementia with Lewy bodies. If the clinician's impression is that the predominant etiology is Alzheimer's disease, the patient may be eligible for Special Authority coverage for cholinesterase inhibitor therapy.



Alzheimer’s Drug Therapy Initiative

FREQUENTLY ASKED QUESTIONS ABOUT COVERAGE OF CHOLINESTERASE INHIBITORS

Table of Contents

1	THE ALZHEIMER’S DRUG THERAPY INITIATIVE	3
1.1	<i>What is the Alzheimer’s Drug Therapy Initiative?</i>	<i>3</i>
1.2	<i>What is the connection between the Alzheimer’s Drug Therapy Initiative and the outcomes research funded by Pharmaceutical Services Division?</i>	<i>3</i>
1.3	<i>Are cholinesterase inhibitors now included in the provincial formulary?</i>	<i>4</i>
1.4	<i>How is this evaluation different from that done by other provinces? Why is it unique and how does it add to our knowledge of the efficacy of these medications?</i>	<i>4</i>
1.5	<i>Will there be any additional compensation for physicians caring for patients with Alzheimer’s disease?</i>	<i>4</i>
2	PRESCRIBING CHOLINESTERASE INHIBITORS UNDER THE ADTI	5
2.1	<i>Are nurse practitioners eligible to prescribe cholinesterase inhibitors?</i>	<i>5</i>
2.2	<i>What is the rationale behind the selected eligibility criteria?</i>	<i>5</i>
2.3	<i>How can I better determine which cholinesterase inhibitor is most appropriate as a first-line agent for my patient? Second-line agent?</i>	<i>5</i>
2.4	<i>In Section 4 (Medication Requested) of the Special Authority Initial Coverage form, for donepezil, should the dose increase be 2.5 mg if frail?</i>	<i>5</i>
2.5	<i>Is a washout period necessary prior to switching to a new cholinesterase inhibitor?</i>	<i>5</i>
2.6	<i>Why is it important to know if a patient is currently taking memantine?</i>	<i>6</i>
2.7	<i>If a patient is being treated with memantine, are the dosages listed on the Special Authority forms still appropriate?</i>	<i>6</i>
2.8	<i>Is coverage going to be provided for memantine (Ebixa®)?</i>	<i>7</i>
2.9	<i>What contraindications should be considering when determining whether my patient should be treated with a cholinesterase inhibitor?</i>	<i>7</i>
2.10	<i>Can I try all three cholinesterase inhibitors successively, if needed?</i>	<i>7</i>
2.11	<i>How do I counsel the patient and their caregiver(s) about discontinuing a cholinesterase inhibitor once it becomes clear that the patient is in a more advanced stage of dementia? Will my patient’s symptoms worsen on discontinuation of the medication?</i>	<i>7</i>
3	ELIGIBILITY CRITERIA.....	8
3.1	<i>Are patients already taking a cholinesterase inhibitor eligible for coverage of their medication?</i>	<i>8</i>
3.2	<i>When filling out the Special Authority form for initial coverage, may I submit the results of an SMMSE done by another GP, medical trainee, nurse, OT, etc? How recent does the SMMSE have to be?</i>	<i>8</i>

3.3	<i>Once I have a baseline SMMSE and Global Deterioration Scale (GDS) stage for a patient, can I use the same scores on subsequent forms, or do I have to repeat them? If so, how often?</i>	8
3.4	<i>Should I expect a patient's SMMSE or GDS stage to improve while they are taking a cholinesterase inhibitor?</i>	8
3.5	<i>What is the difference between stage 3 and 4 on the Global Deterioration Scale (GDS)?</i>	8
3.6	<i>What is the difference between 'much improved' and 'very much improved' in the Overall Patient Assessment Rating?</i>	9
3.7	<i>How does the Overall Patient Assessment Rating work?</i>	9
3.8	<i>I understand that patients must have an SMMSE score of between 10 and 26 to be eligible for Special Authority approval. What if the patient scores 10? What if the initial score is 25 and rises to 27? Will that patient be eligible for continuing coverage?</i>	10
3.9	<i>My patient's rate of deterioration has slowed, but the eligibility criteria require that there is demonstrated stabilization or improvement during the previous 6 months of therapy. Are they still eligible to continue in the initiative?</i>	10
3.10	<i>Will coverage be granted for the treatment of other dementias such as Vascular Dementia, Dementia with Lewy bodies, Parkinson's Disease Dementia, and Frontotemporal Dementia?</i>	10
3.11	<i>What if my patient does not speak fluent English? Can I still complete the SMMSE?</i>	10
3.12	<i>Why do we need to include the patient's height and weight on the SA form? What should I do if the patient lacks sufficient mobility for such measurement?</i>	11
3.13	<i>Why are there other questions on the Special Authority form about ethnicity, language, vision, hearing, education, etc.?</i>	11
3.14	<i>What is the value in asking if the request is for a therapeutic dose of a cholinesterase inhibitor?</i>	11
3.15	<i>Why must I confirm my confidence that a patient can take the drug safely?</i>	11
4	SPECIAL AUTHORITY PROCESS	12
4.1	<i>How quickly after submitting the requested documentation can my patient anticipate receiving cholinesterase inhibitor coverage?</i>	12
4.2	<i>If a Special Authority form is submitted before the initiative is launched, what will happen to it?</i>	12
4.3	<i>How does using the Special Authority process benefit patient care?</i>	12
4.4	<i>Will patients be eligible for coverage of cholinesterase inhibitors while travelling?</i>	12
4.5	<i>Will Special Authority coverage for cholinesterase inhibitors be granted to patients in care facilities?</i>	12
4.6	<i>Will Special Authority coverage of cholinesterase inhibitors be granted to individuals who are currently covered by the Department of Veterans Affairs?</i>	13
4.7	<i>If a patient is nearing the end of their 6-month medication coverage period and they are unable to come into the office for reassessment for continuation of coverage, will PharmaCare provide them with interim coverage?</i>	13
5	APPEALS	14
5.1	<i>If I feel that a patient would benefit from a cholinesterase inhibitor (or would benefit from continued use of a cholinesterase inhibitor) but they do not (or no longer) meet criteria for coverage, what appeal process is available?</i>	14
5.2	<i>If I have a question regarding Special Authority approval that I cannot find an answer for, is there an expert I can email or call?</i>	14
5.3	<i>If I have a question that I cannot find an answer for, is there an expert I can email or call?</i>	14

1 THE ALZHEIMER'S DRUG THERAPY INITIATIVE

1.1 *What is the Alzheimer's Drug Therapy Initiative?*

The Alzheimer's Drug Therapy Initiative (ADTI) is a four-phase initiative established to address a clinical knowledge gap around the use of cholinesterase inhibitors in individuals diagnosed in the mild to moderate stages of Alzheimer's disease.

Phase 1: Forum

Phase 2: Planning the Study

Phase 3: Conducting the Study

Phase 4: Findings/Conclusions from the Study

- The Alzheimer's forum of July 5, 2006 produced a number of consensus recommendations, provided the overall framework and constitutes the first phase.
- The second phase continued this work and set in place working groups to design the details of the study and plan the educational requirements to ensure safe and professional administration and management of these drugs. The timeframe for this phase is January 2007 to September 2007.
- The third phase is the actual conducting of the study over a three-year period.
- The final phase is the analysis of all the data from information collected and the conclusions resulting from the study. This information will help to inform future Ministry of Health policy decisions on the coverage of cholinesterase inhibitors.

1.2 *What is the connection between the Alzheimer's Drug Therapy Initiative and the outcomes research funded by Pharmaceutical Services Division?*

Evidence concerning the long-term effectiveness and safety of cholinesterase inhibitors in treating Alzheimer's disease is controversial. Rather than waiting for the controversy to be resolved by others, Pharmaceutical Services Division (PSD) will, through the study component of ADTI, be covering cholinesterase inhibitors in order to collect data required to evaluate the effectiveness of these medications.

PSD will be collecting administrative data through the submission of Special Authority forms; this data will be used by PSD for the monitoring and evaluation of the ADTI. This administrative data will also be used by independent health scientists contracted by PSD to design and conduct the peer-reviewed outcomes research and impact evaluation of the ADTI.

The peer-reviewed study is being developed and implemented by a multidisciplinary team of leading independent B.C. researchers at UBC's Division of Neurology and the Centre on Aging at University of Victoria. Researchers will be recruiting physicians, patients and their caregivers to participate in the research. PSD encourages physicians to participate in the evaluation, especially those with patients who have been found to be indeterminate responders to cholinesterase inhibitors.

For more information or to participate in the study, please call 1 866 511-2594 (ALZH) or fax to 1 866 406-0303. The principal investigators, Dr. Neena Chappell, Professor of Sociology, Centre on Aging (phone: 250 472-4465, email: nic@uvic.ca) and Dr. Howard Feldman, Director, UBC Hospital Clinic for Alzheimer's Disease & Related Disorders (phone: 604 822-7979, email: howard.feldman@vch.ca) may be contacted for more specific questions related to participating in the evaluation.

1.3 *Are cholinesterase inhibitors now included in the provincial formulary?*

No. The results of the evaluation of cholinesterase inhibitors will inform future government policy on coverage of cholinesterase inhibitors. As part of the Alzheimer's Drug Therapy Initiative, cholinesterase inhibitors are eligible for limited coverage for the period of the evaluation only, currently anticipated at three years.

1.4 *How is this evaluation different from that done by other provinces? Why is it unique and how does it add to our knowledge of the efficacy of these medications?*

There has been a significant amount of controversy surrounding the benefit of cholinesterase inhibitors in the treatment of Alzheimer's disease. It has been established that not all patients benefit. It is difficult to predict who benefits and for how long. The current study is designed to define who responds, what is their response and the duration of their response. The proposed research design will provide an extremely large set of data that will be subject to rigorous scientific evaluation which should, over time, improve our understanding of the effects of cholinesterase inhibitors. The patient management algorithm used in the ADTI is an advance on those used by other provinces that were exclusively based on the Mini-Mental State Examination. The use of the algorithm is integral to the clinical treatment of individuals with Alzheimer's disease.

1.5 *Will there be any additional compensation for physicians caring for patients with Alzheimer's disease?*

The Ministry of Health recognizes that proper dementia care is time-consuming and may not be appropriately compensated through the 0100 (Office Visit) fee. This issue was raised at the August General Practitioners Services Committee (GPSC). Representatives of MSP and the BCMA Tariff Committee present at that meeting confirmed that it is their interpretation of the preamble for the 0120 (Individual Counselling) fee that this fee can be used for GP administration of a Standardized Mini-Mental Status Examination as would be required under the Alzheimer Drug Therapy Initiative.

GPSC also agreed that the Community Patient Conferencing Fee (14015) cannot be billed for the simple initiation of treatment, but more substantive conferencing with a pharmacist about the patient's overall profile and care might qualify, if all other criteria for this fee item were met.

A mental health initiative is currently under development by GPSC that is expected to be launched January, 2008. It is anticipated that this initiative will provide another reimbursement opportunity for general practitioners caring for individuals with Alzheimer's disease.

2 PRESCRIBING CHOLINESTERASE INHIBITORS UNDER THE ADTI

2.1 Are nurse practitioners eligible to prescribe cholinesterase inhibitors?

Nurse practitioners are able to prescribe drugs within the limits of the nurse-practitioner scope of practice and individual competencies within that scope of practice. Nurse practitioners should check with the College of Registered Nurses of B.C. to determine whether they are able to prescribe cholinesterase inhibitors. PharmaCare will accept Special Authority requests from all clinicians able to prescribe these drugs within the limits of their scope of practice.

2.2 What is the rationale behind the selected eligibility criteria?

The eligibility criteria are intended to assist physicians in identifying patients with mild to moderate Alzheimer's disease, where cholinesterase inhibitors may improve or stabilize the patient's cognition, functional abilities and/or behaviour. At the same time, the criteria are also intended to prevent the long-term use of these drugs when they no longer make a difference in the life of a patient with Alzheimer's disease. The Alzheimer's Drug Therapy Initiative seeks to better determine which groups of individuals with Alzheimer's disease are most likely to benefit from these medications.

2.3 How can I better determine which cholinesterase inhibitor is most appropriate as a first-line agent for my patient? Second-line agent?

There is no convincing evidence to date of clinical superiority of one agent over the others. Determination of which cholinesterase inhibitors to use as a first or second-line agent should be guided by the potential adverse effects of each agent, their known drug-drug interactions, and the patient's ability to comply with the required dosing schedule.

2.4 In Section 4 (Medication Requested) of the Special Authority Initial Coverage form, for donepezil, should the dose increase be 2.5 mg if frail?

No. Use standard titration as recommended.

2.5 Is a washout period necessary prior to switching to a new cholinesterase inhibitor?

If a current cholinesterase inhibitor trial is being discontinued due to poor tolerability, a washout period is required prior to switching to a new one. It generally takes a washout period of 2 – 7 days to resolve side effects before starting on another cholinesterase inhibitor; however, do not start the new cholinesterase inhibitor until there has been a resolution of all the previous cholinesterase inhibitor's side effects.

Please refer to the **Guide to Prescribing Cholinesterase Inhibitors** included in this package for detailed dosage instructions. A copy of the reference guide is included below:

CURRENT DRUG TO BE DISCONTINUED DUE TO POOR TOLERABILITY			
STOP	DONEPEZIL	GALANTAMINE	RIVASTIGMINE
WAIT	5 to 7 days	2 days	2 days
START	galantamine or rivastigmine	donepezil or rivastigmine	galantamine or donepezil
Dose/titration of new drug	AS FOR NEW START (see above)		

CURRENT DRUG TO BE TAPERED OFF DUE TO LACK OF EFFICACY (mg daily)				
	Current Dose	End of Week 1	End of Week 2	Maximum Dose**
Donepezil	10	5	0	n/a
	5	2.5		
	2.5	0		
Galantamine	24	16	0	n/a
	16	8		
	8	0		
Rivastigmine (>1.5mg daily, split into twice daily dosing if possible)	12	6	0	n/a
	9	4.5		
	6	3		
	3	1.5		

NEW DRUG TO BE ADDED WHILE CURRENT DRUG TAPERED (mg daily)				
	Current Dose	End of Week 1	End of Week 2	Maximum Dose**
Donepezil OR	-	5 (2.5 if frail)	5	10
Galantamine OR	-	8	16	24
Rivastigmine	-	1.5 to 3 twice daily	6 to 12	12 (6 twice daily)

****Titrate to maximum dose if tolerated and clinically indicated.**

The Special Authority form for renewal/switching of cholinesterase inhibitors must be submitted and approved by PharmaCare in order for your patient to receive coverage for a second cholinesterase inhibitor trial.

2.6 Why is it important to know if a patient is currently taking memantine?

For evaluation purposes, it is important to know whether the patient is on other therapy that might affect treatment response.

2.7 If a patient is being treated with memantine, are the dosages listed on the Special Authority forms still appropriate?

Yes.

2.8 *Is coverage going to be provided for memantine (Ebixa®)?*

No, the Alzheimer's Drug Therapy Initiative will only be providing coverage of the cholinesterase inhibitors donepezil (Aricept®), galantamine (Reminyl®) and rivastigmine (Exelon®).

2.9 *What contraindications should be considered when determining whether my patient should be treated with a cholinesterase inhibitor?*

Clinicians should always use their clinical judgment when making a determination as to whether there are contraindications to treating with cholinesterase inhibitors. The conditions to consider when making this determination are:

- peptic ulcer disease
- hepatic or renal disease
- significant bradycardia or AV block
- significant bronchospastic disease
- obstructive urinary disease
- epilepsy
- history of seizures or
- drug interactions.

2.10 *Can I try all three cholinesterase inhibitors successively, if needed?*

The design of the Alzheimer's Drug Therapy Initiative is such that patients will be eligible for coverage of all three available cholinesterase inhibitors. Please note that there **will not** be concurrent coverage; PharmaCare will only cover one cholinesterase inhibitor at a time.

2.11 *How do I counsel the patient and their caregiver(s) about discontinuing a cholinesterase inhibitor once it becomes clear that the patient is in a more advanced stage of dementia? Will my patient's symptoms worsen on discontinuation of the medication?*

Following protocol, patients in a more advanced stage of dementia no longer meet eligibility criteria for the Alzheimer's Drug Therapy Initiative and would not receive ongoing coverage of cholinesterase inhibitors.

There is insufficient published evidence that cholinesterase inhibitors meaningfully impact functional behaviours in patients with severe dementia. In more advanced stages of the disease, physicians and caregivers should also reevaluate the need to continue other medications, which may also no longer benefit the patient.

There can be withdrawal effects. However, if a patient's symptoms worsen, they should be reviewed promptly by their physician. The patient/caregiver may opt to continue treatment with cholinesterase inhibitors at their own expense, or the physician may request a review through the standard Special Authority process.

3 ELIGIBILITY CRITERIA

3.1 *Are patients already taking a cholinesterase inhibitor eligible for coverage of their medication?*

Yes, they need only meet the outlined eligibility criteria. Please note that cholinesterase inhibitor coverage is effective from the date PharmaCare's Special Authority approval is granted and is not retroactive.

PharmaCare coverage under the ADTI is subject to the patient's plan, annual deductible and family maximums.

3.2 *When filling out the Special Authority form for initial coverage, may I submit the results of an SMMSE done by another GP, medical trainee, nurse, OT, etc? How recent does the SMMSE have to be?*

Physicians may use recent SMMSE results done by another clinician provided they are confident that the test was conducted and scored using the standardized protocol. The SMMSE should not have been done more than two months prior to submitting the request for Special Authority approval.

3.3 *Once I have a baseline SMMSE and Global Deterioration Scale (GDS) stage for a patient, can I use the same scores on subsequent forms, or do I have to repeat them? If so, how often?*

The SMMSE and GDS must be repeated every 6 months from the time of the initial Special Authority approval. The scores must be documented on the Special Authority request for renewal of coverage in order for patients to continue to receive medication coverage through PharmaCare.

3.4 *Should I expect a patient's SMMSE or GDS stage to improve while they are taking a cholinesterase inhibitor?*

Although these measures of cognition and function may improve after initiation of a *cholinesterase inhibitor*, a more realistic goal is for stabilization of the disease or slowing of the rate of decline. Some patients, however, show no response and *cholinesterase inhibitor* therapy should be discontinued.

Note: A patient's GDS stage will increase as Alzheimer's disease progresses. This is why the Overall Patient Assessment Rating is used on the Special Authority application for continuing therapy.

3.5 *What is the difference between stage 3 and 4 on the Global Deterioration Scale (GDS)?*

A GDS of 4 indicates clear-cut dementia where there is obvious impairment and functional disability to support a diagnosis of dementia. A GDS of 3 indicates potential

incipient Alzheimer’s disease, where the disease is not sufficiently documented to make a firm diagnosis. A patient should **not** be treated with a cholinesterase inhibitor if they have a GDS of 3: mild cognitive impairment.

3.6 What is the difference between ‘much improved’ and ‘very much improved’ in the Overall Patient Assessment Rating?

Very much improved designates an unusually robust response to treatment and there should be a positive response on all four assessment measures.

3.7 How does the Overall Patient Assessment Rating work?

In this case, the patient had a mild stroke or temporary mobility issues:

Change in Ability		<u>Improved (+1) / No Change (0) / Worse (-1)</u>
Cognition	A. Memory, reasoning and perception: e.g. names, tasks, SMMSE	<u>+1</u>
Function	B. Instrumental Activities of Daily Living: e.g. telephone, shopping, meal preparation	<u>-1</u>
	C. Basic Activities of Daily Living: e.g. bathing, dressing, hygiene and toileting	<u>-1</u>
Behaviour	D. Neuropsychiatric Symptoms: e.g. agitation, delusions, hallucination, apathy	<u>-1</u>
Total Score (A+B+C+D) =		<u><u>-2</u></u>

In this example, the patient only had a mild deterioration in assessment measures B, C and D while there was a slight improvement in cognition that could indicate that the patient’s current cholinesterase inhibitor is still effective.

If there was a direct conversion from the **Total Score** to the Overall Patient Assessment Rating, the patient would be rated as a “much worse” and deemed to be a “Non-Responder”; accordingly, PharmaCare would not renew coverage of the patient’s cholinesterase inhibitor. This demonstrates why it is important that a physician uses their clinical judgment and takes into account other factors affecting the Overall Patient Assessment Rating rather than using the Total Score to determine whether a patient should continue to receive the drug.

Therefore, in this scenario, although the Total Score is -2, clinical judgment could rate the overall patient assessment rating as minimally worse overall rather than much worse and coverage would continue.

3.8 *I understand that patients must have an SMMSE score of between 10 and 26 to be eligible for Special Authority approval. What if the patient scores 10? What if the initial score is 25 and rises to 27? Will that patient be eligible for continuing coverage?*

For initial coverage, the SMMSE score must be ≥ 10 to ≤ 26 AND the Global Deterioration Scale stage must be 4, 5, or 6, AND the patient must have a clinical dementia of the (predominantly) Alzheimer type. If the patient's SMMSE score rises above 26 on treatment, the patient would be considered a treatment responder and coverage would be continued.

If the patient's SMMSE score is less than 10, they would be a non-responder and coverage would be discontinued.

3.9 *My patient's rate of deterioration has slowed, but the eligibility criteria require that there is demonstrated stabilization or improvement during the previous 6 months of therapy. Are they still eligible to continue in the initiative?*

Yes. If, in your clinical judgment, the patient's deterioration is "minimally worse," then they would meet the assessment criterion for an indeterminate responder and thus still be eligible for continued PharmaCare coverage within the initiative.

3.10 *Will coverage be granted for the treatment of other dementias such as Vascular Dementia, Dementia with Lewy bodies, Parkinson's Disease Dementia, and Frontotemporal Dementia?*

No. Cholinesterase inhibitors are only approved by Health Canada for the indication of Alzheimer's disease and are not recommended for off-label use.

For the purposes of the ADTI, Special Authority for cholinesterase inhibitor treatment is granted only for Alzheimer-type dementia or for a mixed dementia where the predominant etiology is Alzheimer's disease. Coverage would not be granted for pure vascular dementia, pure dementia with Lewy bodies, and pure Parkinson's disease dementia. However, many cases of vascular dementia, pure dementia with Lewy bodies, and pure Parkinson's disease dementia are actually mixed dementia. If the clinician's assessment is that the *predominant* etiology is Alzheimer's disease, then coverage would be granted. Please note that cholinesterase inhibitor therapy is not generally effective for frontotemporal dementia.

3.11 *What if my patient does not speak fluent English? Can I still complete the SMMSE?*

If the patient has sufficient English to proceed with the SMMSE, it can be conducted in English. If the patient's English is insufficient to proceed, an attempt should be made to involve a translator. Where a translator is unavailable, you would need to check the box "functionally illiterate."

If the patient's language skills are not sufficient to enable them to complete the SMMSE, you would need to check the box 'functionally illiterate.'

3.12 *Why do we need to include the patient's height and weight on the SA form? What should I do if the patient lacks sufficient mobility for such measurement?*

These are required for evaluation purposes. You may use a best estimate if the patient cannot be weighed or measured.

3.13 *Why are there other questions on the Special Authority form about ethnicity, language, vision, hearing, education, etc.?*

PharmaCare wants to know if patient characteristics affect tolerability or can be used to predict a better or worse response to cholinesterase inhibitor therapy.

3.14 *What is the value in asking if the request is for a therapeutic dose of a cholinesterase inhibitor?*

The benefits of cholinesterase inhibitor therapy are modest at best and randomized trials indicate very little benefit from subtherapeutic doses.

3.15 *Why must I confirm my confidence that a patient can take the drug safely?*

This is required for Special Authority approval. The benefits of cholinesterase inhibitor therapy are limited and there are potential side effects such as nausea and vomiting or cardiac effect (bradycardia) from overdosing. It is important that patients be able to take their medications reliably, especially when living alone. If the prescribing physician does not believe their patient can take the drug safely, PharmaCare will not approve coverage for that patient.

4 SPECIAL AUTHORITY PROCESS

4.1 *How quickly after submitting the requested documentation can my patient anticipate receiving cholinesterase inhibitor coverage?*

Once PharmaCare has received, reviewed and approved the completed Special Authority request for initial coverage of a cholinesterase inhibitor, assuming the patient meets the eligibility criteria, they will receive drug coverage. The length of time required to review each request will depend on the volume of requests being submitted but is not anticipated to take longer than two weeks.

Patients filling prescriptions outside the Special Authority approval period will not receive PharmaCare coverage. Individuals with Alzheimer's disease participating in the Alzheimer's Drug Therapy Initiative should check with their local pharmacist that Special Authority approval has been granted before filling prescriptions for cholinesterase inhibitors.

For continued coverage, renewal requests must be submitted every six months.

It is important that follow-up appointments are scheduled at least two weeks before Special Authority approval expires to ensure there is no gap in PharmaCare coverage.

4.2 *If a Special Authority form is submitted before the initiative is launched, what will happen to it?*

Special Authority forms received before the launch date will be held and processed after the official launch.

4.3 *How does using the Special Authority process benefit patient care?*

The Special Authority process for the Alzheimer's Drug Therapy Initiative allows for the overall management of the patient through optimal use of medication and reduces the negative impact of prolonged or poorly-monitored response to treatment. The process, including the 6-month assessment period, is also designed to provide data for associated studies.

4.4 *Will patients be eligible for coverage of cholinesterase inhibitors while travelling?*

Special Authority may consider coverage of cholinesterase inhibitors for patients required to travel. For consideration of such requests, please contact the Special Authority Unit directly by fax to 1 800 609-4884.

4.5 *Will Special Authority coverage for cholinesterase inhibitors be granted to patients in care facilities?*

Yes, if they meet the eligibility criteria.

*Note: Individuals in acute care hospitals or extended care hospitals are **not** eligible for PharmaCare coverage; health authorities are responsible for the provision of medications to individuals residing in these health care facilities. It is up to the health authority whether the facility's formulary includes cholinesterase inhibitors.*

When your patient moves to one of these facilities, you should advise the facility's medical director that their patient is being treated with a cholinesterase inhibitor and that this treatment should not be abruptly terminated.

4.6 *Will Special Authority coverage of cholinesterase inhibitors be granted to individuals who are currently covered by the Department of Veterans Affairs?*

In general, no. If these individuals already have drug coverage through the Government of Canada, they are not eligible for coverage by PharmaCare. However, your patient should contact the PharmaCare Helpline at 1 800 663-7100 to confirm whether or not they have PharmaCare coverage.

4.7 *If a patient is nearing the end of their 6-month medication coverage period and they are unable to come into the office for reassessment for continuation of coverage, will PharmaCare provide them with interim coverage?*

Coverage is terminated at 6-month intervals unless PharmaCare receives the next, complete Special Authority renewal form, indicating that the patient continues to meet eligibility criteria. If the appropriate documentation has not been submitted, as in the case of a patient not being able to come into the office, the patient will either have to pay for the medication out-of-pocket, use sample medication, or go without the medication until they can be seen and the necessary paperwork completed.

Retroactive coverage will not be provided. For continued coverage, renewal requests must be submitted every six months. It is therefore important to stress to patients and caregivers to book successive appointments at least two weeks before their Special Authority approval ends.

5 APPEALS

- 5.1 *If I feel that a patient would benefit from a cholinesterase inhibitor (or would benefit from continued use of a cholinesterase inhibitor) but they do not (or no longer) meet criteria for coverage, what appeal process is available?*

AND

- 5.2 *If I have a question regarding Special Authority approval that I cannot find an answer for, is there an expert I can email or call?*

There is no formal appeal process; however, if you disagree with a decision made by the Special Authority unit, please fax your concerns to them directly.

You may submit any questions regarding Special Authority approval for cholinesterase inhibitors in writing to the Special Authority fax number: 1 800 609-4884. Special Authority pharmacists and clinical experts may review Special Authority decisions provided there is sufficient documentation to support reconsideration.

- 5.3 *If I have a question that I cannot find an answer for, is there an expert I can email or call?*

All questions, clinical and administrative, should be directed to Health Insurance BC (HIBC). HIBC is the organization charged with addressing queries from clinicians, pharmacists and patients. If there are clinical questions which they cannot answer, these will be referred to Special Authority staff. You may contact HIBC at 1 800 663-7100.

SPECIAL AUTHORITY FORMS

- Reference Guide to Completing Special Authority Forms
- Initial Coverage
- Renewal/Switching Coverage

Pads of forms are attached with the accompanying SMMSE and GDS documents, and a patient handout.



Alzheimer's Drug Therapy Initiative

REFERENCE GUIDE TO COMPLETING SPECIAL AUTHORITY FORMS FOR PRESCRIBERS

The Special Authority process – general description

Special Authority grants full benefit status to a medication that would otherwise not be considered for full or partial coverage. Special Authority forms must be faxed to the Special Authority fax number at 1 800 609-4884. Forms are reviewed for completeness and faxed back to the clinician with the dates of approval or a request for further information.

If you have any questions regarding Special Authority forms or the Special Authority process, please submit them in writing to the Special Authority Unit fax number at 1 800 609-4884.

Special Authority forms

Two Special Authority forms are being used for the Alzheimer's Drug Therapy Initiative (ADTI). A link to the current Special Authority forms for cholinesterase inhibitors is provided on the ADTI website at www.health.gov.bc.ca/pharme/adti/.

1. Initial Coverage (6 months) – pad includes the Standardized Mini-Mental State Examination (SMMSE) and Global Deterioration Scale (GDS), and 2-page patient handout (invitation to learn more about the Centre on Aging Study and information sheet) - 4 double-sided pages
2. Renewal/Switching (submitted at 6 month intervals for renewal / as required for switching) – pad includes SMMSE and GDS – 4 double-sided pages

Following is a step-by-step process to assist clinicians in completing the initial Special Authority form. Please note that forms will be returned if information is missing.

How to complete the Special Authority form for initial coverage of cholinesterase inhibitors

As indicated on the form, in order to be eligible to receive coverage of cholinesterase inhibitors through the ADTI, patients must meet the eligibility criteria.

1. Under Section 3 - Patient Information, use the check box to indicate the type of diagnosis of Alzheimer's disease applicable to your patient.
2. Conduct the Standardized Mini-Mental State Examination (SMMSE) accompanying the Special Authority form and note your patient's score and their Global Deterioration Scale (GDS) stage in the spaces provided. *Please note that a SMMSE score of ≥ 10 to ≤ 26 and a GDS of ≥ 4 to ≤ 6 are required for participation in the ADTI.*
3. If you experience difficulty in conducting the assessment tests with your patient, please note if functionally illiterate in the check box and proceed to GDS.
4. Answer the three questions before the drug selection table. These are required fields.
5. In Section 4, put a check mark beside the cholinesterase inhibitor you have selected to start your patient on. Brief dosing/titration guidelines are provided for easy reference.
6. Hand out invitation to patient/caregiver to participate in follow-up studies.



**SPECIAL AUTHORITY REQUEST
CHOLINESTERASE INHIBITORS
INITIAL COVERAGE (6 MONTHS)
ALZHEIMER'S DRUG THERAPY INITIATIVE**

Fax requests in Victoria to 952-1065 or, from elsewhere in BC, to 1 800 609-4884 (toll free)
OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

This facsimile is Doctor-Patient privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited. If you have received this fax in error, please write "MIS-DIRECTED" across the front of the form and fax toll-free to 1 800 609-4884, then destroy the pages received in error.

Should approval be granted for this Special Authority request, PharmaCare's authorization is solely for the purpose of providing prescription benefit for the cost of the requested medication. PharmaCare makes no representation about the suitability of the requested medication for the patient's medical condition or any other problem.

Forms with information missing will be returned for completion.

ELIGIBILITY CRITERIA: Diagnosis of Alzheimer's Disease with SMMSE of ≥ 10 to ≤ 26 and Global Deterioration Scale ≥ 4 to ≤ 6

SECTION 1 - PRESCRIBER INFORMATION

NAME & MAILING ADDRESS <input type="checkbox"/> MAIL CONFIRMATION	APPLICATION DATE YYYY MM DD	PRESCRIBER'S TEL # AREA CODE
	PRESCRIBER'S COLLEGE ID #	PRESCRIBER'S FAX # AREA CODE

SECTION 2 - PATIENT INFORMATION

PERSONAL HEALTH NUMBER (PHN)	PATIENT (FAMILY) NAME
DATE OF BIRTH (YYYY / MM / DD)	PATIENT (GIVEN) NAME(S)

SECTION 3 - CRITERIA FOR INITIAL COVERAGE OF A 6-MONTH SUPPLY

DIAGNOSIS OF: <input type="checkbox"/> ALZHEIMER'S DISEASE <input type="checkbox"/> ALZHEIMER'S DISEASE WITH VASCULAR COMPONENT <input type="checkbox"/> ALZHEIMER'S DISEASE WITH PARKINSONIAN FEATURES (LEWY BODIES) <input type="checkbox"/> ALZHEIMER'S DISEASE WITH OTHER (SPECIFY): _____	ASSESSMENT SCORES SMMSE (10-26) _____ GDS (4-6) _____	COMPLETE THE FOLLOWING: <input type="checkbox"/> VISION / HEARING IMPAIRED <input type="checkbox"/> LANGUAGE BARRIER <input type="checkbox"/> LIVES ALONE ETHNIC ANCESTRY (CHECK ONE ONLY) <input type="checkbox"/> ABORIGINAL <input type="checkbox"/> LATIN AMERICAN <input type="checkbox"/> MIDDLE EASTERN <input type="checkbox"/> AFRICAN <input type="checkbox"/> EUROPEAN <input type="checkbox"/> OTHER: _____ <input type="checkbox"/> ASIAN <input type="checkbox"/> SOUTH ASIAN
DOES THE PATIENT RESIDE IN A HEALTH CARE FACILITY WHERE MEDICAL CARE IS PROVIDED? <input type="checkbox"/> YES <input type="checkbox"/> NO	FUNCTIONALLY ILLITERATE <input type="checkbox"/> YES <input type="checkbox"/> NO	YEARS OF EDUCATION (CHECK ONE ONLY) <input type="checkbox"/> 0 - 8 <input type="checkbox"/> 9 - 12 <input type="checkbox"/> 13+ HEIGHT: _____ (CM) WEIGHT: _____ (KG)

SECTION 4 - MEDICATION REQUESTED (MONTHLY FILLS)

IS PATIENT CURRENTLY TAKING MEMANTINE? <input type="checkbox"/> YES <input type="checkbox"/> NO	HAVE YOU CHECKED FOR CONTRAINDICATIONS? <input type="checkbox"/> YES <input type="checkbox"/> NO	DOES THE PATIENT HAVE THE ABILITY OR SOCIAL SUPPORT TO PROPERLY TAKE THE MEDICATION? <input type="checkbox"/> YES <input type="checkbox"/> NO		
	STARTING DOSE	TITRATION AS TOLERATED	EFFECTIVE RANGE	MAXIMUM DAILY DOSE
<input type="checkbox"/> DONEPEZIL	5 mg daily (2.5 mg if frail) for 4 to 6 weeks	increase by 5 mg	5 to 10 mg daily	10 mg
<input type="checkbox"/> GALANTAMINE	8 mg ER daily for 4 to 6 weeks	increase by 8 mg	16 to 24 mg daily	24 mg
<input type="checkbox"/> RIVASTIGMINE (divided dose)	1.5 mg twice daily for 2 to 4 weeks	increase by 1.5 to 3 mg twice daily	6 to 12 mg daily	12 mg (6 mg twice daily)

I have read and understood the educational materials provided by the Alzheimer's Drug Therapy Initiative. Yes No

Personal information on this form is collected for the operations of the Ministry of Health. The Ministry will use the information in the decision to provide PharmaCare benefits for the medication requested, and for implementation, monitoring, evaluation and research of this and other Ministry programs, and for the management and planning of the health system generally. Personal information will be used and disclosed in accordance with the privacy protection provisions of the Freedom of Information and Protection of Privacy Act. If you have any questions about the collection of this information, call Health Insurance BC from Vancouver at 604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient the purpose of the release of the patient's information to PharmaCare to obtain Special Authority for prescription benefit and for the purposes set out above.

Signature of Prescriber (Mandatory)

Patient Signature (Optional)

PharmaCare may request additional documentation to support this Special Authority request.

PHARMACARE USE ONLY

STATUS	EFFECTIVE DATE
	DURATION OF COVERAGE

GLOBAL DETERIORATION SCALE (GDS)

Stage	Deficits in cognition and function	Usual care setting	Mean MMSE
1	Subjectively and objectively normal	Independent	29-30
2	Subjective complaints of mild memory loss. Objectively normal on testing. No functional deficit	Independent	29
3	Mild Cognitive Impairment (MCI) Earliest clear-cut deficits. Functionally normal but co-workers may be aware of declining work performance. Objective deficits on testing. Denial may appear.	Independent	25
4	Early dementia Clear-cut deficits on careful clinical interview. Difficulty performing complex tasks, e.g. handling finances, travelling. Denial is common. Withdrawal from challenging situations.	Might live independently – perhaps with assistance from family or caregivers.	20
5	Moderate dementia Can no longer survive without some assistance. Unable to recall major relevant aspects of their current lives, e.g. an address or telephone number of many years, names of grandchildren, etc. Some disorientation to date, day of week, season, or to place. They require no assistance with toileting, eating, or dressing but may need help choosing appropriate clothing.	At home with live-in family member. In seniors' residence with home support. Possibly in facility care, especially if behavioural problems or comorbid physical disabilities.	14
6	Moderately severe dementia May occasionally forget name of spouse. Largely unaware of recent experiences and events in their lives. Will require assistance with basic ADLs. May be incontinent of urine. Behavioural and psychological symptoms of dementia (BPSD) are common, e.g. delusions, repetitive behaviours, agitation.	Most often in Complex Care facility.	5
7	Severe dementia Verbal abilities will be lost over the course of this stage. Incontinent. Needs assistance with feeding. Lose ability to walk.	Complex Care	0

Adapted by Dr. Doug Drummond from Reisberg B, Ferris SH, Leon MJ, et al. The global deterioration scale for assessment of primary degenerative dementia. American Journal of Psychiatry 1982;139:1136-1139.

STANDARDIZED MINI-MENTAL STATE EXAMINATION (SMMSE)

NAME OF PATIENT

DATE

Directions for administration of the SSMSE:

1. Before the questionnaire is administered, try to get the person to sit down facing you. Assess the person's ability to hear and understand very simple conversation, e.g. *What is your name?* If the person uses hearing or visual aids, provide these before starting.
2. Introduce yourself and try to get the person's confidence. Before you begin, get the person's permission to ask questions, e.g. *Would it be alright to ask you the same questions about your memory?* This helps to avoid catastrophic reactions.
3. Ask each question a maximum of three times. If the subject does not respond, score 0.
4. If the person answers incorrectly, score 0. Accept that answer and do not ask the question again, hint, or provide any physical clues such as head shaking, etc.
5. The following equipment is required to administer the instrument: A watch, a pencil, Page 3 of this SMMSE with **CLOSE YOUR EYES** written in large letters and two five-sided figures intersecting to make a four-sided figure, and Page 4, a blank piece of paper.
6. If the person answers: *What did you say?*, do not explain or engage in conversation. Merely repeat the same directions a maximum of three times.
7. If the person interrupts (e.g. *What is this for?*), reply: *I will explain in a few minutes, when we are finished. Now if we could proceed please... we are almost finished.*

I am going to ask you some questions and give you some problems to solve. Please try to answer as best as you can.

1. Time: 10 seconds for each reply:

- | | |
|--|----|
| a) <i>What year is this?</i> (accept exact answer only). | /1 |
| b) <i>What season is this?</i> (accept either: last week of the old season or first week of a new season). | /1 |
| c) <i>What month is this?</i> (accept either: the first day of a new month or the last day of the previous month). | /1 |
| d) <i>What is today's date?</i> (accept previous or next date). | /1 |
| e) <i>What day of the week is this?</i> (accept exact answer only). | /1 |

2. Time: 10 seconds for each reply:

- | | |
|---|----|
| a) <i>What country are we in?</i> (accept exact answer only). | /1 |
| b) <i>What province are we in?</i> (accept exact answer only). | /1 |
| c) <i>What city/town are we in?</i> (accept exact answer only). | /1 |
| d) (In home) <i>What is the street address of this house?</i> (accept street name and house number or equivalent in rural areas). | |
| (In facility) <i>What is the name of this building?</i> (accept exact name of institution only). | /1 |
| e) (In home) <i>What room are we in?</i> (accept exact answer only). | |
| (In facility) <i>What floor of the building are we on?</i> (accept exact answer only). | /1 |

3. Time: 20 seconds

Say: *I am going to name three objects. When I am finished, I want you to repeat them. Remember what they are because I am going to ask you to name them again in a few minutes.* (Say the following words slowly at approximately one-second intervals): *Ball / Car / Man.*

For repeated use: Bell, jar, fan; Bill, tar, can; Bull, bar, pan.

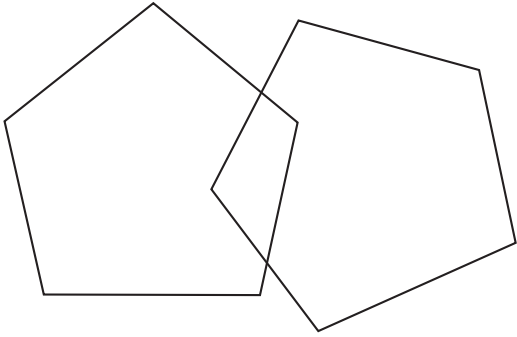
Please repeat the three items for me. (score one point for each correct reply on the first attempt.)

If the person did not repeat all three, repeat until they are learned or up to a maximum of five times (but only score first attempt).

/3

4. Time: 30 seconds Spell the word WORLD. (you may help the person to spell the word correctly) Say: <i>Now spell it backwards please.</i> If the subject cannot spell world even with assistance, score 0. Refer to Page 3 for scoring instructions.	/5
5. Time: 10 seconds Say: <i>Now what were the three objects I asked you to remember?</i> (score one point for each correct answer regardless of order)	/3
6. Time: 10 seconds Show wristwatch. Ask: <i>What is this called?</i> (score one point for correct response: accept “wristwatch” or “watch”; do not accept “clock” or “time”, etc.).	/1
7. Time: 10 seconds Show pencil. Ask: <i>What is this called?</i> (score one point for correct response; accept “pencil” only; score 0 for pen)	/1
8. Time: 10 seconds Say: <i>I would like you to repeat a phrase after me: No ifs, ands or buts.</i> Score one point for a correct repetition. Must be exact, e.g. no ifs or buts, score 0).	/1
9. Time: 10 seconds Say: <i>Read the words on this page and then do what it says.</i> Then, hand the person the sheet with CLOSE YOUR EYES on it. If the subject just reads and does not close eyes, you may repeat: <i>Read the words on this page and then do what it says</i> (a maximum of three times). Score one point only if the subject closes eyes. The subject does not have to read aloud.	/1
10. Time: 30 seconds Hand the person a pencil and paper (Page 3). Say: <i>Write any complete sentence on that piece of paper.</i> Score one point. The sentence must make sense. Ignore spelling errors.	/1
11. Time: 1 minute maximum Place design, eraser and pencil in front of the person. Say: <i>Copy this design please.</i> Allow multiple tries. Wait until the person is finished and hands it back. Score one point for a correctly copied diagram. The person must have drawn a four-sided figure between two five-sided figures.	/1
12. Time: 30 seconds Ask the person if he is right or left handed. Take a piece of paper, hold it up in front of the person and say: <i>Take this paper in your right/left hand (whichever is non-dominant), fold the paper in half once with both hands and put the paper down on the floor.</i> Score one point for each instruction executed correctly.	
	Takes paper in correct hand /1
	Folds it in half /1
	Puts it on the floor /1
	Total Test Score: /30
	Adjusted Score /

Please note: This tool is provided for use in British Columbia with permission by Dr. D. William Molloy. This questionnaire should not be further modified or reproduced without the written consent of Dr. D. William Molloy. Molloy DW, Alemayehu E, Roberts R. Reliability of a standardized Mini-Mental State Examination compared with the traditional Mini-Mental State Examination. American Journal of Psychiatry, 1991; 148(1): 102-105.



Foldline

Scoring WORLD backwards (instructions for item #4)

Write the person's response below the correct response.
 Draw lines matching the same letters in the correct response and the response given.
 These lines MUST NOT cross each other.
 The person's score is the maximum number of lines that can be drawn without crossing any.

Examples:

D	L	R	O	W
D	L	R	O	W

 = Score 5

D	L	R	O	W
		/	/	/
D	R	W	O	D

 = Score 3

D	L	R	O	W
/		/	/	/
L	O	W	R	O

 = Score 3

D	L	R	O	W
/				
L				

 = Score 1

D	L	R	O	W
	/	/	/	/
L	R	R	W	O

 = Score 3

D	L	R	O	W

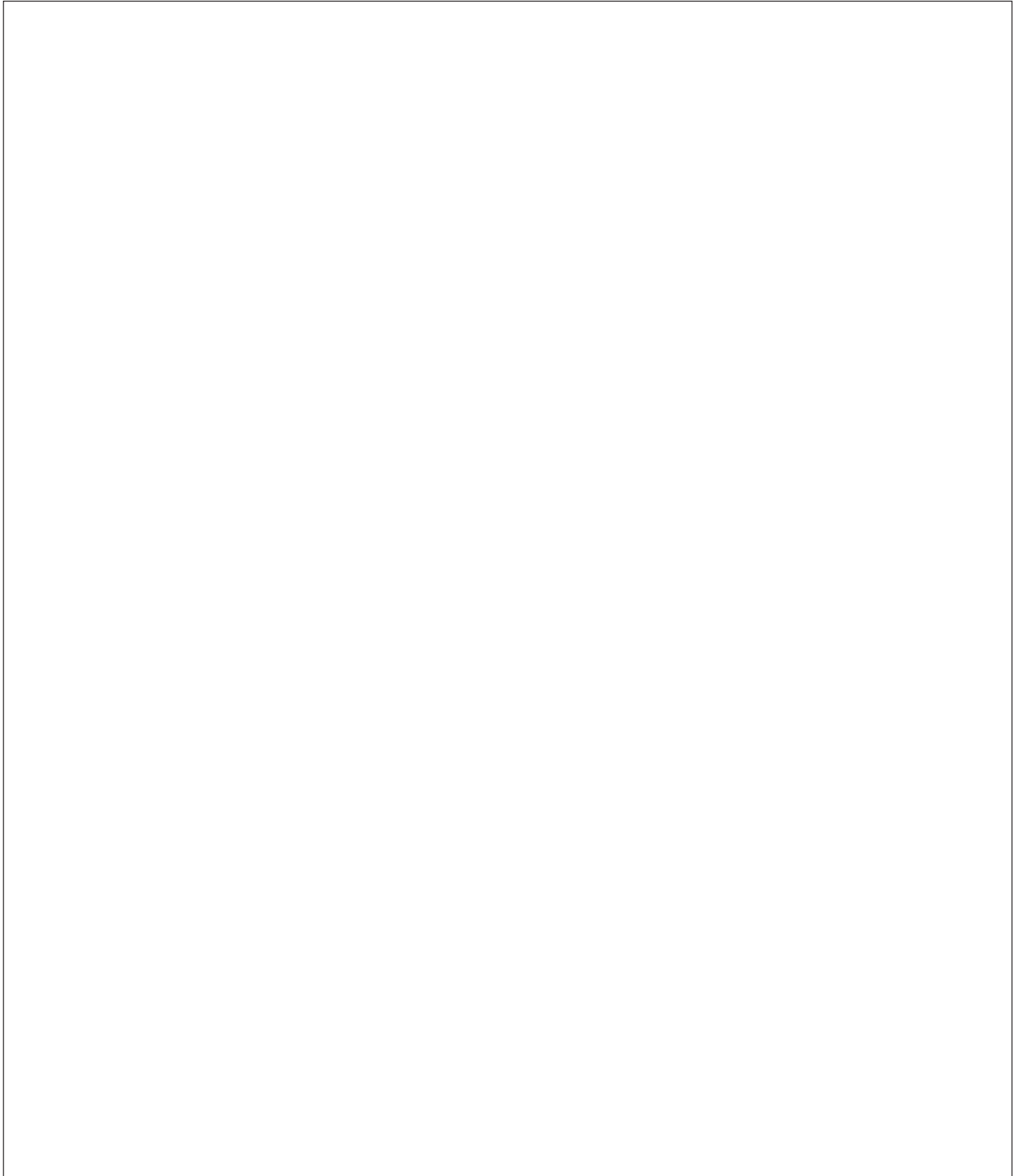
 = _____

Fold along this line and show instructions to person

Close your eyes

Item 10

Sentence Writing

A large, empty rectangular box with a thin black border, intended for the student to write their sentence.



University
of Victoria

Centre on Aging
PO BOX 1700, STN CSC
Victoria, British Columbia
Canada V8W 2Y2
Phone: (250) 721-6369 Fax: (250) 721-6499
www.coag.uvic.ca

Dear Patient/Caregiver:

You, or someone you care for, has been prescribed a medication for the treatment of Alzheimer's disease.

Doctors say the long-term benefits of drugs for individuals affected by Alzheimer's disease are not well-studied.

As part of two new studies to learn more about your experiences with these medications, the Centre on Aging at the University of Victoria has been asked to interview individuals affected by Alzheimer's disease, their families and caregivers.

This is a only a preliminary invitation for you to gather more information about these studies. For information, please phone the Centre on Aging at:

1 866 511-2594 (ALZH)

Staff at the Centre will explain the studies to you and send you a letter to help you decide whether to participate. Calling us is voluntary and will not enrol you in any study.

Also, whether you participate or not does not affect your PharmaCare coverage of this medication in any way. Any information you share with us will be confidential, protected by regulations for ethics in research.

We appreciate you taking the time to consider gathering more information about participating in these studies.

Sincerely,

Dr. Neena Chappell
Canada Research Chair on Aging
Centre on Aging
University of Victoria



Alzheimer's Drug Therapy Initiative

INFORMATION FOR INDIVIDUALS AFFECTED BY ALZHEIMER'S DISEASE

On October 22, 2007, as part of the Alzheimer's Drug Therapy Initiative, certain drugs called cholinesterase inhibitors will become eligible for PharmaCare coverage for people participating in the initiative.

These drugs do not cure Alzheimer's disease but they may help slow its progression in some people in the mild to moderate stages.

Although not all persons with Alzheimer's disease will benefit from receiving coverage of these medications, if you feel that you or a member of your family may benefit, you should arrange a visit to your family doctor. They will ask you some questions to determine whether or not you are eligible to participate in the initiative.

If you have already been prescribed these drugs and your physician determines that you are eligible to participate in the initiative, PharmaCare will also grant Special Authority approval for coverage of these medications, subject to your plan, annual deductible and family maximum.

If you are able to participate and agree to take the medication, you will be asked to visit your doctor at least once every 6 months for follow-up visits to see how you are doing. It is important that these visits be scheduled at least three weeks before Special Authority approval ends to ensure there is no break in coverage.

Interviews with individuals, families and caregivers affected by Alzheimer's disease are an important component of this research. We encourage you to contact the Centre on Aging at the University of Victoria at 1 866 511-2594 (ALZH) to participate in follow-up studies.

More information is available on the Alzheimer's Drug Therapy Initiative website at www.health.gov.bc.ca/pharme/adi/ or you may call HIBC at 1 800 663-7100.



SPECIAL AUTHORITY REQUEST
CHOLINESTERASE INHIBITORS
RENEWAL/SWITCHING COVERAGE (6 MONTHS)
ALZHEIMER'S DRUG THERAPY INITIATIVE

RENEWAL

complete sections 1, 2, 3, 5 and 7

SWITCHING (TOLERABILITY)

complete sections 1, 2, 3, 4 and 7

SWITCHING (EFFICACY)

complete sections 1, 2, 3, 5, 6 and 7

Fax requests in Victoria to 952-1065 or, from elsewhere in BC, to 1 800 609-4884 (toll free)
OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

This facsimile is Doctor-Patient privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited. If you have received this fax in error, please write "MIS-DIRECTED" across the front of the form and fax toll-free to 1 800 609-4884, then destroy the pages received in error.

Should approval be granted for this Special Authority request, PharmaCare's authorization is solely for the purpose of providing prescription benefit for the cost of the requested medication. PharmaCare makes no representation about the suitability of the requested medication for the patient's medical condition or any other problem.

Forms with information missing will be returned for completion.

ELIGIBILITY CRITERIA: Diagnosis of Alzheimer's Disease with SMMSE of ≥ 10 , Global Deterioration Scale ≥ 4 to ≤ 6

SECTION 1 – PRESCRIBER INFORMATION

NAME & MAILING ADDRESS	<input type="checkbox"/> MAIL CONFIRMATION	APPLICATION DATE YYYY MM DD	PRESCRIBER'S TEL # AREA CODE
		PRESCRIBER'S COLLEGE ID #	PRESCRIBER'S FAX # AREA CODE

SECTION 2 – PATIENT INFORMATION

PERSONAL HEALTH NUMBER (PHN)	PATIENT (FAMILY) NAME
DATE OF BIRTH (YYYY / MM / DD)	PATIENT (GIVEN) NAME(S)

SECTION 3 – CLINICAL INFORMATION

DOES THE PATIENT RESIDE IN A HEALTH CARE FACILITY WHERE MEDICAL CARE IS PROVIDED? <input type="checkbox"/> YES <input type="checkbox"/> NO	IS PATIENT CURRENTLY TAKING MEMANTINE? <input type="checkbox"/> YES <input type="checkbox"/> NO	HAVE YOU CHECKED FOR CONTRAINDICATIONS? <input type="checkbox"/> YES <input type="checkbox"/> NO
DOES THE PATIENT HAVE THE ABILITY OR SOCIAL SUPPORT TO PROPERLY TAKE THE MEDICATION? <input type="checkbox"/> YES <input type="checkbox"/> NO	HEIGHT: _____ (CM) WEIGHT: _____ (KG)	

SECTION 4 – SWITCHING FOR LACK OF TOLERABILITY (for lack of efficacy, go to Section 5)

1. Stop current cholinesterase inhibitor 2. Allow washout period of 2 days for galantamine and rivastigmine, or 5 to 7 days for donepezil 3. Start new cholinesterase inhibitor using the same titration schedule as new starts		
CHOLINESTERASE INHIBITOR BEING DISCONTINUED	DATE TREATMENT STOPPED (YYYY / MM / DD)	DOSAGE
NOTED SIDE EFFECTS		

PHARMACARE USE ONLY

STATUS	EFFECTIVE DATE	DURATION OF COVERAGE

CHOLINESTERASE INHIBITORS RENEWAL/SWITCHING COVERAGE (6 MONTHS)

PATIENT NAME	PHN	DATE OF BIRTH (YYYY / MM / DD)
--------------	-----	--------------------------------

SECTION 5 – PATIENT ASSESSMENT FOR RENEWING OR SWITCHING FOR LACK OF EFFICACY

STEP 1	LAST 6-MONTH SMMSE SCORE	CURRENT SMMSE SCORE	DIFFERENCE	<input type="checkbox"/> UNABLE TO COMPLETE SMMSE BECAUSE OF FUNCTIONAL ILLITERACY	GDS STAGE
ASSESS THE CHANGE IN ABILITY OVER THE LAST SIX MONTHS.					
STEP 2	COGNITION	A. MEMORY, REASONING AND PERCEPTION (E.G. NAMES, TASKS, SMMSE) _____		(+1 = IMPROVED, 0 = NO CHANGE, -1 = WORSE)	
	FUNCTION	B. INSTRUMENTS OF DAILY LIVING (E.G. TELEPHONE, SHOPPING, MEAL PREPARATION) _____		(+1 = IMPROVED, 0 = NO CHANGE, -1 = WORSE)	
		C. BASIC ACTIVITIES OF DAILY LIVING (E.G. BATHING, DRESSING, HYGIENE AND TOILETING) _____		(+1 = IMPROVED, 0 = NO CHANGE, -1 = WORSE)	
	BEHAVIOUR	D. NEUROPSYCHIATRIC SYMPTOMS (E.G. AGITATION, DELUSIONS, HALLUCINATION, APATHY) _____		(+1 = IMPROVED, 0 = NO CHANGE, -1 = WORSE)	
TOTAL SCORE (A+B+C+D): _____					
STEP 3	TOTAL SCORE	→ CLINICAL JUDGMENT →	OVERALL PATIENT ASSESSMENT RATING		RECOMMENDATION
	+4		<input type="checkbox"/> VERY MUCH IMPROVED	POSITIVE RESPONDER	CONTINUE TREATMENT; RE-EVALUATE PATIENT EVERY 6 MONTHS
	+3 OR +2		<input type="checkbox"/> MUCH IMPROVED		
	+1		<input type="checkbox"/> MINIMALLY IMPROVED		
	0		<input type="checkbox"/> NO CHANGE	INDETERMINATE RESPONDER	CONTINUE TREATMENT; RE-EVALUATE PATIENT EVERY 6 MONTHS (CONSIDER SWITCHING CHOLINESTERASE INHIBITOR).
	-1		<input type="checkbox"/> MINIMALLY WORSE		
	-2 OR -3		<input type="checkbox"/> MUCH WORSE	NON-RESPONDER	
-4	<input type="checkbox"/> VERY MUCH WORSE				
ELIGIBILITY CRITERIA - DIAGNOSIS OF ALZHEIMER'S DISEASE WITH SMMSE ≥10, GDS 4 TO 6, OVERALL PATIENT ASSESSMENT RATING OF POSITIVE RESPONDER OR INDETERMINATE RESPONDER.					

SECTION 6 – SWITCHING FOR LACK OF EFFICACY (Refer to Guide to Prescribing for Titration of New Cholinesterase Inhibitor)

CHOLINESTERASE INHIBITOR BEING DISCONTINUED	DATE TREATMENT STOPPED (YYYY / MM / DD)	DOSAGE
---	---	--------

SECTION 7 – MEDICATION REQUESTED (MONTHLY FILLS)

	STARTING DOSE	TITRATION AS TOLERATED	EFFECTIVE RANGE	MAXIMUM DAILY DOSE
<input type="checkbox"/> DONEPEZIL	5 mg daily (2.5 mg if frail) for 4 to 6 weeks	increase by 5 mg	5 to 10 mg daily	10 mg
<input type="checkbox"/> GALANTAMINE	8 mg ER daily for 4 to 6 weeks	increase by 8 mg	16 to 24 mg daily	24 mg
<input type="checkbox"/> RIVASTIGMINE (divided dose)	1.5 mg twice daily for 2 to 4 weeks	increase by 1.5 to 3 mg twice daily	6 to 12 mg daily	12 mg (6 mg twice daily)

IF REQUESTING LESS THAN THE THERAPEUTIC DOSE, PLEASE STATE WHY

I have read and understood the educational materials provided by the Alzheimer's Drug Therapy Initiative. Yes No

Personal information on this form is collected for the operations of the Ministry of Health. The Ministry will use the information in the decision to provide PharmaCare benefits for the medication requested, and for implementation, monitoring, evaluation, and research of this and other Ministry programs, and for the management and planning of the health system generally. Personal information will be used and disclosed in accordance with the privacy protection provisions of the Freedom of Information and Protection of Privacy Act. If you have any questions about the collection of this information, call Health Insurance BC from Vancouver at 604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient the purpose of the release of the patient's information to PharmaCare to obtain Special Authority for prescription benefit and for the purposes set out above.

Signature of Prescriber (Mandatory)

Patient Signature (Optional)

PharmaCare may request additional documentation to support this Special Authority request.

STANDARDIZED MINI-MENTAL STATE EXAMINATION (SMMSE)

NAME OF PATIENT

DATE

Directions for administration of the SSMSE:

1. Before the questionnaire is administered, try to get the person to sit down facing you. Assess the person's ability to hear and understand very simple conversation, e.g. *What is your name?* If the person uses hearing or visual aids, provide these before starting.
2. Introduce yourself and try to get the person's confidence. Before you begin, get the person's permission to ask questions, e.g. *Would it be alright to ask you the same questions about your memory?* This helps to avoid catastrophic reactions.
3. Ask each question a maximum of three times. If the subject does not respond, score 0.
4. If the person answers incorrectly, score 0. Accept that answer and do not ask the question again, hint, or provide any physical clues such as head shaking, etc.
5. The following equipment is required to administer the instrument: A watch, a pencil, Page 3 of this SMMSE with **CLOSE YOUR EYES** written in large letters and two five-sided figures intersecting to make a four-sided figure, and Page 4, a blank piece of paper.
6. If the person answers: *What did you say?*, do not explain or engage in conversation. Merely repeat the same directions a maximum of three times.
7. If the person interrupts (e.g. *What is this for?*), reply: *I will explain in a few minutes, when we are finished. Now if we could proceed please... we are almost finished.*

I am going to ask you some questions and give you some problems to solve. Please try to answer as best as you can.

1. Time: 10 seconds for each reply:

- | | |
|--|----|
| a) <i>What year is this?</i> (accept exact answer only). | /1 |
| b) <i>What season is this?</i> (accept either: last week of the old season or first week of a new season). | /1 |
| c) <i>What month is this?</i> (accept either: the first day of a new month or the last day of the previous month). | /1 |
| d) <i>What is today's date?</i> (accept previous or next date). | /1 |
| e) <i>What day of the week is this?</i> (accept exact answer only). | /1 |

2. Time: 10 seconds for each reply:

- | | |
|---|----|
| a) <i>What country are we in?</i> (accept exact answer only). | /1 |
| b) <i>What province are we in?</i> (accept exact answer only). | /1 |
| c) <i>What city/town are we in?</i> (accept exact answer only). | /1 |
| d) (In home) <i>What is the street address of this house?</i> (accept street name and house number or equivalent in rural areas). | |
| (In facility) <i>What is the name of this building?</i> (accept exact name of institution only). | /1 |
| e) (In home) <i>What room are we in?</i> (accept exact answer only). | |
| (In facility) <i>What floor of the building are we on?</i> (accept exact answer only). | /1 |

3. Time: 20 seconds

Say: *I am going to name three objects. When I am finished, I want you to repeat them. Remember what they are because I am going to ask you to name them again in a few minutes.* (Say the following words slowly at approximately one-second intervals): *Ball / Car / Man.*

For repeated use: Bell, jar, fan; Bill, tar, can; Bull, bar, pan.

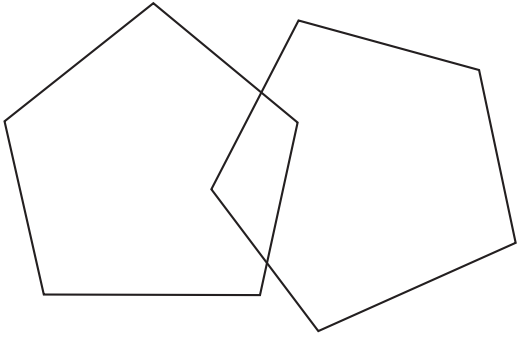
Please repeat the three items for me. (score one point for each correct reply on the first attempt.)

If the person did not repeat all three, repeat until they are learned or up to a maximum of five times (but only score first attempt).

/3

4. Time: 30 seconds Spell the word WORLD. (you may help the person to spell the word correctly) Say: <i>Now spell it backwards please.</i> If the subject cannot spell world even with assistance, score 0. Refer to Page 3 for scoring instructions.	/5
5. Time: 10 seconds Say: <i>Now what were the three objects I asked you to remember?</i> (score one point for each correct answer regardless of order)	/3
6. Time: 10 seconds Show wristwatch. Ask: <i>What is this called?</i> (score one point for correct response: accept “wristwatch” or “watch”; do not accept “clock” or “time”, etc.).	/1
7. Time: 10 seconds Show pencil. Ask: <i>What is this called?</i> (score one point for correct response; accept “pencil” only; score 0 for pen)	/1
8. Time: 10 seconds Say: <i>I would like you to repeat a phrase after me: No ifs, ands or buts.</i> Score one point for a correct repetition. Must be exact, e.g. no ifs or buts, score 0).	/1
9. Time: 10 seconds Say: <i>Read the words on this page and then do what it says.</i> Then, hand the person the sheet with CLOSE YOUR EYES on it. If the subject just reads and does not close eyes, you may repeat: <i>Read the words on this page and then do what it says</i> (a maximum of three times). Score one point only if the subject closes eyes. The subject does not have to read aloud.	/1
10. Time: 30 seconds Hand the person a pencil and paper (Page 3). Say: <i>Write any complete sentence on that piece of paper.</i> Score one point. The sentence must make sense. Ignore spelling errors.	/1
11. Time: 1 minute maximum Place design, eraser and pencil in front of the person. Say: <i>Copy this design please.</i> Allow multiple tries. Wait until the person is finished and hands it back. Score one point for a correctly copied diagram. The person must have drawn a four-sided figure between two five-sided figures.	/1
12. Time: 30 seconds Ask the person if he is right or left handed. Take a piece of paper, hold it up in front of the person and say: <i>Take this paper in your right/left hand (whichever is non-dominant), fold the paper in half once with both hands and put the paper down on the floor.</i> Score one point for each instruction executed correctly.	
	Takes paper in correct hand /1
	Folds it in half /1
	Puts it on the floor /1
	Total Test Score: /30
	Adjusted Score /

Please note: This tool is provided for use in British Columbia with permission by Dr. D. William Molloy. This questionnaire should not be further modified or reproduced without the written consent of Dr. D. William Molloy. Molloy DW, Alemayehu E, Roberts R. Reliability of a standardized Mini-Mental State Examination compared with the traditional Mini-Mental State Examination. American Journal of Psychiatry, 1991; 148(1): 102-105.



Foldline

Scoring WORLD backwards (instructions for item #4)

Write the person's response below the correct response.
 Draw lines matching the same letters in the correct response and the response given.
 These lines MUST NOT cross each other.
 The person's score is the maximum number of lines that can be drawn without crossing any.

Examples:

D	L	R	O	W
D	L	R	O	W

= Score 5

D	L	R	O	W
		/	/	/
D	R	W	O	D

= Score 3

D	L	R	O	W
/		/	/	/
L	O	W	R	O

= Score 3

D	L	R	O	W
/				
L				

= Score 1

D	L	R	O	W
	/	/	/	/
L	R	R	W	O

= Score 3

D	L	R	O	W

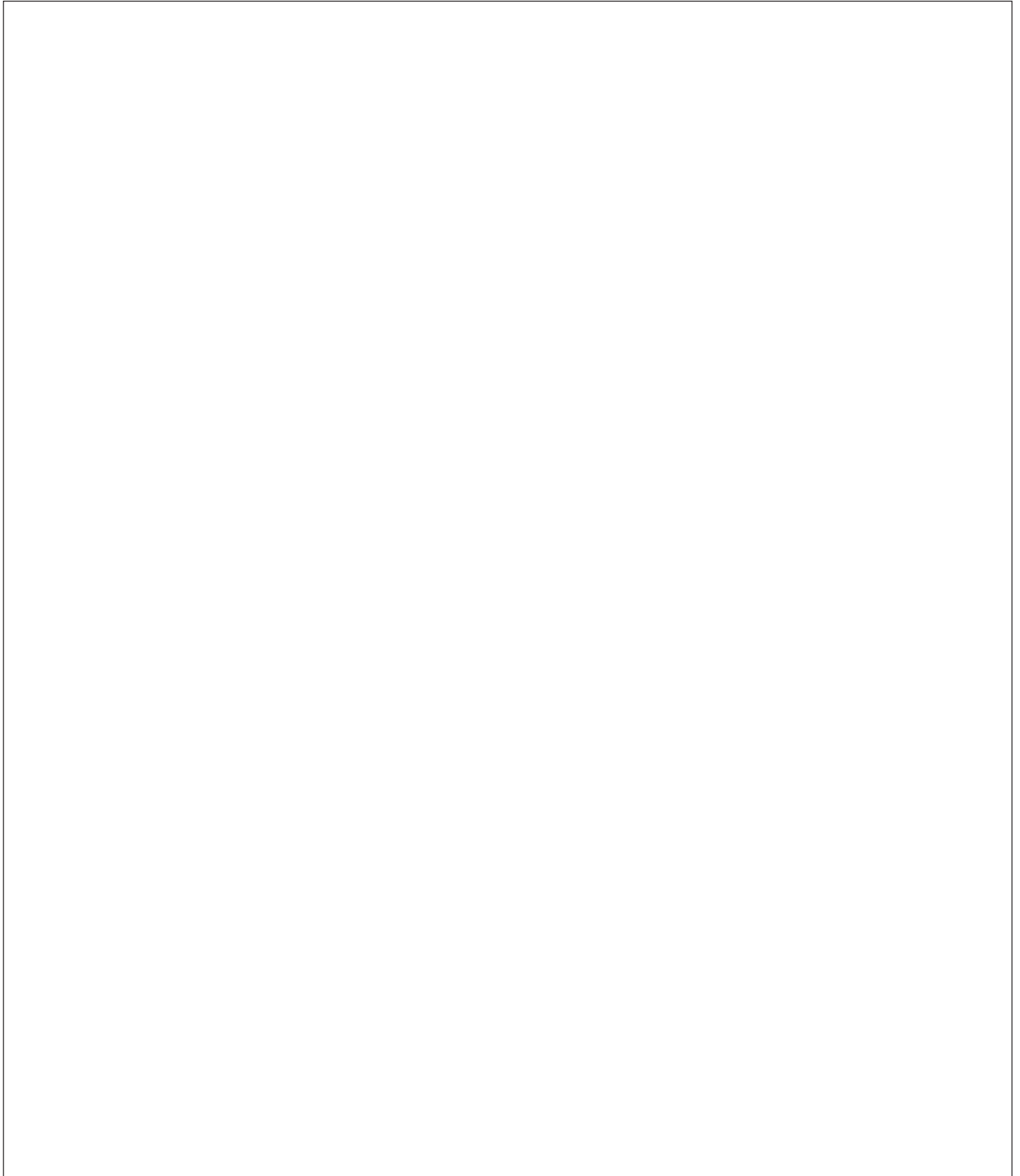
= _____

Fold along this line and show instructions to person

Close your eyes

Item 10

Sentence Writing



GLOBAL DETERIORATION SCALE (GDS)

Stage	Deficits in cognition and function	Usual care setting	Mean MMSE
1	Subjectively and objectively normal	Independent	29-30
2	Subjective complaints of mild memory loss. Objectively normal on testing. No functional deficit	Independent	29
3	Mild Cognitive Impairment (MCI) Earliest clear-cut deficits. Functionally normal but co-workers may be aware of declining work performance. Objective deficits on testing. Denial may appear.	Independent	25
4	Early dementia Clear-cut deficits on careful clinical interview. Difficulty performing complex tasks, e.g. handling finances, travelling. Denial is common. Withdrawal from challenging situations.	Might live independently – perhaps with assistance from family or caregivers.	20
5	Moderate dementia Can no longer survive without some assistance. Unable to recall major relevant aspects of their current lives, e.g. an address or telephone number of many years, names of grandchildren, etc. Some disorientation to date, day of week, season, or to place. They require no assistance with toileting, eating, or dressing but may need help choosing appropriate clothing.	At home with live-in family member. In seniors' residence with home support. Possibly in facility care, especially if behavioural problems or comorbid physical disabilities.	14
6	Moderately severe dementia May occasionally forget name of spouse. Largely unaware of recent experiences and events in their lives. Will require assistance with basic ADLs. May be incontinent of urine. Behavioural and psychological symptoms of dementia (BPSD) are common, e.g. delusions, repetitive behaviours, agitation.	Most often in Complex Care facility.	5
7	Severe dementia Verbal abilities will be lost over the course of this stage. Incontinent. Needs assistance with feeding. Lose ability to walk.	Complex Care	0

Adapted by Dr. Doug Drummond from Reisberg B, Ferris SH, Leon MJ, et al. The global deterioration scale for assessment of primary degenerative dementia. American Journal of Psychiatry 1982;139:1136-1139.



Alzheimer's Drug Therapy Initiative

PHYSICIAN COMMENTS

We appreciate your feedback on the Alzheimer's Drug Therapy Initiative. Please submit your comments or questions to Pharmaceutical Services Division by fax to 1 250 952-2790.
