



Alzheimer's Drug Therapy Initiative

FREQUENTLY ASKED QUESTIONS ABOUT COVERAGE OF CHOLINESTERASE INHIBITORS

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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 Individual Counselling fees (0120 through 18120 and 12220 through 18220) are to be used for counselling patients. Administering the Standardized Mini-Mental State Examination (SMMSE) may be part of that counselling session. The minimum time per visit in order to bill these counselling fees is 20 minutes.

The General Practice Services Committee (GPSC) also agreed that the Community Patient Conference Fee (14016) cannot be billed for the simple initiation of treatment, but more substantive conferencing with a pharmacist about the patient's overall profile and care does qualify, if all other criteria for this fee item were met.

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.

Patients already prescribed a cholinesterase inhibitor are considered non-naive patients. Information on their current cholinesterase inhibitor prescription is available through existing administrative databases.

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:

<u>Change in Ability</u>		<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.