

ALZHEIMER'S DRUG THERAPY INITIATIVE

FREQUENTLY ASKED QUESTIONS ABOUT COVERAGE OF CHOLINESTERASE INHIBITORS

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1 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 was January to September 2007.
- The third phase is conducting the study over a four-year period (October 2007 to March 2012).
- The final phase, scheduled for April 2012, 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 Services' policy decisions on the coverage of cholinesterase inhibitors expected in June 2012.

1.2 *What is the connection between the Alzheimer's Drug Therapy Initiative and the outcomes research conducted by UBC and the University of Victoria?*

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, PSD is, through the ADTI's research component undertaken by UBC and UVic, providing PharmaCare coverage of cholinesterase inhibitors in order to collect the data required to evaluate the effectiveness of these medications.

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

The peer-reviewed study was 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 are recruiting physicians, patients and their caregivers to participate in the research. PSD is encouraging physicians to participate in the evaluation, especially those with patients who have been found to be indeterminate responders to treatment with cholinesterase inhibitors.

For information or to participate in the study, please call 1 866 511-2594 (ALZH) or fax 1 866 406-0303. For specific questions on participation, please contact the principal investigators, Dr. Neena Chappell, Professor of Sociology, UVic's Centre on Aging (phone 250 472-4465, email nlc@uvic.ca) and co-principal investigators, Dr. Lynn Beattie (604 822-7176, email lynn.beattie@vch.ca) and Dr. Phil Lee (604 806-8029, email pelee@providencehealth.bc.ca).

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 to end in 2012.

1.4 *How is this evaluation 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 benefits of cholinesterase inhibitors in the treatment of Alzheimer's disease. It has been established that not all patients benefit and it is difficult to predict who benefits and for how long. The current study is designed to define who responds, what their response is and the duration of their response. The current program provides 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 affected by Alzheimer's disease.

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

The Individual Counseling 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 - \$40/15 min) 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 are met.

The ADTI's Research Compensation Program was launched in July 2009 to provide payment to physicians for providing demographic information on Special Authority forms and for referring and monitoring patients participating in the Seniors' Medication Study (SMS). Fee items 97001 to 97007, ranging from \$15 to \$50 dollars, are available through the MSP billing system for ADTI-related activities.

For more detailed information, please visit the Research Program section of the ADTI's website at: www.health.gov.bc.ca/pharmacare/adti/clinician/research_program.html.

2 PRESCRIBING ChEIs UNDER THE ADTI

2.1 *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.

2.2 *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.

2.3 *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 another. 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 *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 2 to 7 days to resolve side effects; 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** in the October 2007 Clinician Booklet for detailed dosage instructions. The guide can be found at:

www.health.gov.bc.ca/pharmacare/adti/clinician/pdf/SECTION%204%20-%20Reference%20Guide%20to%20Prescribing%20ChEIs.pdf

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.

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)

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

2.5 Is coverage being provided for memantine (Ebixa®)?

No, the Alzheimer's Drug Therapy Initiative is only providing PharmaCare coverage of cholinesterase inhibitors—donepezil (Aricept®), galantamine (Reminyl®) and rivastigmine (Exelon®) capsules and transdermal patch.

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

Yes.

2.7 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 the standard titration as recommended.

2.8 *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 **is no** concurrent coverage; PharmaCare only covers one cholinesterase inhibitor at a time.

2.9 *If I need to switch my patient to another cholinesterase inhibitor, how do I ensure their coverage will continue?*

2.10 *It is advised that a second cholinesterase inhibitor be initiated before the patient's original medication runs out. This will ensure that they have a supply of the original medication on hand should they experience problems with the second drug. Most patients remain on the new drug and do not go back to the old medication.*

2.11 *When my patient no longer appears to be benefiting from the medication and scores below 10 on the SMMSE required for continuing coverage under the ADTI, what is my best course of action?*

Determining when a patient should discontinue treatment is a clinical decision to be made by the physician in consultation with the patient and caregiver. While cost-effectiveness studies supporting the use of cholinesterase inhibitor treatment in patients with severe dementia are limited and controversial (i.e., having a SMMSE score less than 10), patients sometimes react negatively when ChEI treatment is suddenly stopped.

If this is the case, the physician can submit a SA renewal request noting their patient's OPAR was 'much worse or 'very much worse' and write in the comments section that continued coverage is being requested because the patient reacted negatively after the treatment was terminated.

While this renewal process only takes a couple of days, physicians can reduce the impact of any potential delay in coverage renewal by stopping treatment before the original medication runs out so they can go back on their 'left over medication' if there are problems.

3 ELIGIBILITY CRITERIA

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

Yes, they need only meet the stated 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 usual plan, annual deductible and family maximum.

Patients already prescribed a cholinesterase inhibitor are considered non-naïve 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, can I submit the results of an SMMSE conducted by another clinician? 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 be administered no more than 60 days prior to submitting the SA request.

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 renewal request for patients to continue to receive PharmaCare coverage of their cholinesterase inhibitor medication.

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.

3.5 *What is the difference between stages 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>-2</u>

In this example, the patient had only 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 for a physician to use their clinical judgment and take 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? Is that patient eligible for continuing coverage?

For initial coverage, the SMMSE score must be ≥ 10 to ≤ 26 AND the GDS stage must be 4, 5, or 6, AND the patient must have a diagnosis of clinical dementia of the (predominantly) Alzheimer type.

If a patient’s SMMSE score rises above 26 after cholinesterase inhibitor treatment is initiated, the patient is considered a positive responder and coverage would be continued.

If on reassessment the patient’s SMMSE score drops below 10, they would be normally viewed as a non-responder and coverage would be discontinued. However, if the physician’s OPAR assessment is that the patient is an indeterminate responder, coverage would be renewed.

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.

In addition, the Seniors' Medication Study is specifically looking at indeterminate responders. Please contact the University of Victoria's Centre on Aging at sms@uvic.ca or phone the Project Coordinator at 250 721-6574 for more information.

3.10 *Is coverage being 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 mild to moderate 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 mixed dementia where the predominant etiology is Alzheimer's disease. Coverage is not 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 assessment is that the *predominant* etiology is Alzheimer's disease, then coverage will 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. When the patient's language skills are insufficient and no translator is available, please 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 on 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.

The ADTI's Research Compensation Program provides payment to physicians for providing this demographic information. Please visit the ADTI's website at

www.health.gov.bc.ca/pharmacare/adti/clinician/research_program.html for more information.

4 SPECIAL AUTHORITY PROCESS

4.1 *How soon after submitting the Special Authority request will my patient receive 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 for those prescriptions. Individuals with Alzheimer's disease participating in the ADTI should check with their local pharmacist or HIBC that Special Authority approval has been granted before filling their prescription.

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 *Are patients eligible for coverage of cholinesterase inhibitors while travelling?*

According to PharmaCare policy, a patient is now allowed to fill a prescription before the usual 14-day refill requirement for travel outside B.C.

Once every six months (180 days), a patient may top up their existing prescription supply to the maximum 30 days' supply. To be eligible for PharmaCare coverage, the patient must complete and sign a Travel Declaration form (supplied by the pharmacy) on the date the prescription(s) is filled.

If more than a 30 days' supply is requested, the patient is responsible for any remaining cost and only the 30-day supply counts towards the patient's deductible and and/or family maximum.

4.3 *Is Special Authority coverage for cholinesterase inhibitors granted to patients in care facilities?*

Yes, if they meet the eligibility criteria.

Note: Individuals in acute care hospitals or extended care hospitals are eligible for PharmaCare coverage of cholinesterase inhibitors only if the health authority has agreed to participate in the ADTI.

When a patient moves to one of these facilities, please advise the facility's medical director that the patient is being treated with a cholinesterase inhibitor and that this treatment should be continued.

4.4 *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.

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

Coverage will be terminated unless PharmaCare receives the subsequent Special Authority renewal form, indicating that the patient continues to meet eligibility criteria. To avoid the loss of coverage due to appointments delays, a grace period of 4 weeks has been added to the 6-month coverage period.

Without current Special Authority approval, 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 is not provided.

APPEALS

4.6 *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

4.7 *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.

4.8 *If I have a question that I cannot find an answer for, is there an expert I can contact?*

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.

5 ADTI BILLING RULES AND RESEARCH COMPENSATION

5.1 *What fee items are applicable to physicians who wish to participate in the ADTI and, in particular, the research component of the Initiative?*

A variety of related fee items are available to general practitioners and specialists participating in the ADTI. For examples of what fee items to bill for patient management and care, please see the Dementia Services Billing Framework included with this package of materials.

For information on ADTI-specific fee items for providing research information (97001 to 97007), please refer to the MSP fee items listed in the Research Program materials available at www.health.gov.bc.ca/pharmacare/adi/clinician/research_program.html.

Additional information is also provided in question 1.5.

6 COVERAGE FOR EXTENDED CARE RESIDENTS

6.1 *Are patients in Extended Care hospitals eligible to participate in the ADTI research studies?*

No. While PharmaCare coverage of cholinesterase inhibitors is available for residents of extended care hospitals under health authority jurisdiction, because their drug history is not recorded in PharmaNet, ADTI researchers are unable to access the information needed for the studies.

Similarly, residents of long-term care facilities under PharmaCare's Plan B may participate in the ADTI as long as they meet the eligibility criteria but they are not eligible to participate in the research portion of the ADTI as they do not meet the caregiver requirement.

For residents of Extended Care hospitals, physicians CANNOT bill fee items 97001 to 97007 as these patients are excluded from the research component of the ADTI.