Coverage for Cholinesterase Inhibitors by Canadian Jurisdictions

1. Summary of Canadian Public Plan Listings for Cognitive Enhancers[1]													
Drug	**Brand/generic**	**BC**	**AB**	**SK**	**MB**	**ON**	**QC**	**NB**	**NS**	**PEI**	**NL**	**YK**	**NIHB/ NU/ NW**
Donepezil	Aricept, generic	Res	Res	Res	Res	Pas	Res	Res	Res	Res	Res	Res	Res
	Aricept RDT, generic	No	No	No	No	No	Res	No	No	No	No	No	No
Rivastigmine	Exelon, generic	Res	Res	Res	Res	Pas	Res	Res	Res	Res	Res	Res	Res
	Exelon oral solution	Res	Res	Res	No	Res	Res	Res	Res	No	Res	No	Res
	Exelon patch	Res	No	No	No	No	Res	No	No	No	No	Res	No
Galantamine	Reminyl, generic	Res	Res	Res	Res	Pas	Res	Res	Res	Res	Res	Res	Res
Memantine	Ebixa, generic	No	No	No	No	No	Res	No	No	No	No	No	No

1 Excerpt from draft report on Cognitive Enhancers for Treatment of Alzheimer's Disease by The Ontario Drug Policy Research Network
No=not listed
Pas=restricted listing – passive (e.g., Limited Use in Ontario)
Res=restricted listing – enforced
FB=full benefit
Current as of April 24, 2015

2. Summary of Canadian Public Plan Criteria for Coverage of Cholinesterase Inhibitors (ChEI):

- **donepezil (ARICEPT®),**
- **galantamine (REMINYL®), and**
- **rivastigmine (EXELON®)**

Date Completed:	**August 14, 2015**	
Drug	**Status**	**Details**
British Columbia	UR	
Alberta	LWC	For the treatment of Alzheimer's disease in patients with an MMSE (Mini Mental State Exam) score between 10-26 and/or an InterRAI-Cognitive Performance Scale score between 1 and 4. Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's disease (donepezil, galantamine, rivastigmine) when these medications are intended for use in combination. Special authorization coverage may be granted for a maximum of 24 months per request.

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		For each request, an updated MMSE score or InterRAI-Cognitive Performance Scale score and the date on which the exam was administered must be provided. Renewal requests may be considered for patients where the updated MMSE score is 10 or higher or the InterRAI-Cognitive Performance Scale is 4 or lower while on this drug." Coverage is available for Aricept 5 and 10mg, Reminyl 8, 16 and 24 mg and Exelon 1.5, 2, 3, 4.5 and 6 mg (and listed interchangeable generics for all products, where applicable).
Manitoba	LWC	Confirmed diagnosis of Alzheimer Disease based on DSMIV criteria with: 1. memory impairment (impaired ability to learn new information or to recall previously learned information); PLUS 2. at least one of the following: * Aphasia; problems with language (receptive and expressive) * Apraxia; impaired ability to carry out motor activities despite intact motor function * Agnosia; failure of recognition, especially people * Disturbance in executive functioning and 3. The above deficits must have: 4. Caused significant decline in function from previous levels; and 5. A gradual onset and continued cognitive decline; and 6. The absence of other causative conditions; and 7. The deficits do not occur exclusively during the course of delirium. And 8. Normal test results for all of the following values: CBC, TSH, Electrolytes, Vitamin B12, and Glucose. And 9. The initial MMSE score must be between 10 and 26, and measured within 30 days of the application.

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		For continuance of coverage, the patient must have shown improvement or stabilization of symptoms and the MMSE score must be maintained above 10, and measured within 30 days of the application.
New Brunswick	LWC	For a patient being started on a first ChEI: Patients who meet all of the following reimbursement criteria will be approved for an initial 6 months of therapy: • a diagnosis of probable Alzheimer's disease or possible Alzheimer's disease with vascular component or Lewy bodies; • a Mini Mental Score Exam (MMSE) score of 10 to 30; and • a Functional Assessment & Staging Test (FAST) score of 4 to 5. For a patient who has previously taken no more than one other ChEI and is switching: Patients will be approved for an initial 6 months of therapy with a second ChEI when the following information is provided: • the reason for discontinuing the first ChEI Requests to switch from one agent in the class to another will not be considered beyond the initial 6 month approval. To continue therapy for 1 year period (once initial 6 month approval has been completed): Patients who meet the following monitoring criteria will be approved for 1 year periods of therapy: • MMSE score of 10 to 30 (Note: MMSE score must be provided 6 months after starting a ChEI and then only annually thereafter.); AND • FAST score of 4 to 5 (Note: FAST score must be provided 6 months after starting a ChEI and then only

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		annually thereafter.) Note: Monitoring of target symptoms will no longer be required; however, physicians will be asked at the initial and subsequent reassessments if, in their opinion, the patient is benefiting from the drug.
Newfoundland & Labrador	LWC	For the treatment of patients with a diagnosis of mild to moderate Alzheimer's Disease or possible Alzheimer's Disease with vascular component, with Lewy bodies or other (as specified) who meet the following criteria: Initiation of coverage of a cholinesterase inhibitor (ChEI) - New Request: Patients who meet all of the following reimbursement criteria will be approved for an initial 180 days of therapy. Coverage is provided for an initial 180 days when all the following criteria are met: • A Mini-Mental State Examination (MMSE) score of 10 to 30 AND; • A Functional Assessment Staging Test (FAST) score of 4 to 5; and Request for Continuation of Cholinesterase Inhibitor - Renewal Request: Patients who meet the following monitoring criteria will be approved for 12 months of therapy at a time: • A MMSE score of 10 to 30 (Note: A MMSE test must be performed no sooner than 2 months prior to the expiry date of the previous approval of the ChEI.); • A FAST score of 4 to 5 (Note: A FAST test must be performed no sooner than 2 months prior to the expiry date of the previous approval of the ChEI.); and • Evidence of benefit: Is the patient benefiting from this drug? Please describe. (only for initial reassessment) When is it time to consider discontinuing the cholinesterase inhibitor? • If the MMSE < 10 or FAST ≥6 (not eligible for coverage) OR • There is no initial improvement after 3-6 months of therapy OR

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		• The patient has a rapid decline in cognitive or functional symptoms OR • Rapid decline in MMSE (>3 points in 6 months) or FAST FAST STAGE FUNCTIONAL IMPAIRMENT DUE TO COGNITIVE DEFICIT (NOT PHYSICAL) 4 Mild IADLs: needs assistance (Instrumental Activities of Daily Living include complex tasks such as managing money and medications, shopping, cooking, driving, housekeeping, using telephone) 5 Moderate Re-wearing clothes; requires assistance in such basic tasks of daily life as choosing proper clothing. Patient can no longer function independently 6 Moderately Severe ADLs: needs assistance, especially with dressing and bathing (i.e. unable to bathe properly; inability to handle the mechanics of toileting); eventually experiences urinary and fecal incontinence (Activities of Daily Living include dressing, washing, toileting, feeding, mobility) 7 Severe Non-verbal, non-ambulatory Stage 4: Patients with mild Alzheimer's disease may demonstrate problems with recent memory, which impairs their ability to manage their instrumental activities of daily living (IADL). • These patients may still be quite capable of managing their own basic activities of daily living (ADL). • This would be associated with a FAST of 4. Stage 5: Patient exhibits deficient performance in such basic tasks of daily life such as choosing proper clothing, and assistance is required for independent community living. Functional Impairment is due to cognitive deficit and not a physical deficit. • The caregiver must help the patient choose appropriate clothing for the occasion or season. (e.g. the patient will wear incongruous clothing) • Over the course of this stage some patients may begin to forget to bathe regularly, unless reminded. • Patients at this stage are still capable of putting on their clothing properly, once it has been selected for them.

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		They are also capable of bathing themselves although they may have been reminded to bathe. • This should represent a change from previous behaviour. Note: Patients with moderate Alzheimer's disease will have more difficulty with their IADL and may require cueing to manage their basic ADL (e.g., assistance to choose proper clothing) but are able to complete the task with some degree of independence. This would be associated with a FAST of 5. Stage 6: Decreased ability to dress, bathe, and toilet independently Substage 6(a): Decreased ability to put on clothing properly. Patient requires actual physical assistance in putting on clothing properly. As the illness advances, increasing assistance from caregivers is needed to help the patients clothe themselves properly (e.g. putting on clothing in the proper sequence, putting shoes on proper feet, buttoning or zipping clothing). Substage 6(b): Decreased ability to bathe independently. Ability to properly adjust the bathwater, enter and exit the bath, wash properly, and completely dry oneself declines. Patient may have a fear of bathing. Substage 6(c): Decreased ability to perform mechanics of toileting independently. Patients at this stage begin to forget to flush the toilet. They may also begin to forget to wipe themselves or wipe themselves improperly when toileting. The caregiver begins to assist the patient in the mechanics of toileting. Substage 6(d): Urinary incontinence and 6(e): Fecal Incontinence. This is in the absence of infection or other genitourinary tract, or gastrointestinal, pathology. The patient has episodes of incontinence.

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		Note: If there is a reason unrelated to Alzheimer's dementia that a patient meets the criteria for a score of 6 on the FAST scale (e.g., they have urinary incontinence secondary to pre-existing stress incontinence, or dressing difficulties due to arthritis), that criterion should be ignored when determining the patient's FAST stage.
Nova Scotia	LWC	Donepezil, Galantamine, Rivastigmine for the treatment of mild to moderate probable Alzheimer's disease or possible Alzheimer's disease with vascular component, with Lewy bodies who meet the following criteria: • a Mini-Mental State Examination (MMSE) score of 10 to 30 AND • a Functional Assessment Staging Test (FAST) score of 4 to 5 Initial requests for reimbursement will be considered for a maximum 4 month approval; subsequent requests may be considered for a maximum 12 month approval. Requests to switch from one agent in the class to another will not be considered beyond the initial 4 month approval
Ontario	Limited Use (Restricted listing – passive)	Initial Trial: For patients with mild to moderate Alzheimer's Disease (Mini-Mental State Exam [MMSE] 10-26). Patients will be reimbursed for a period of up to 3 months after which continued treatment must be reassessed. Limited Use Authorization Period: 1 year Continuation: Further reimbursement will be made available to those patients whose disease has not progressed/deteriorated while on this drug. Patients must continue to have a MMSE score of 10-26. Limited Use Authorization Period: 1 year
Prince Edward Island	LWC	Donepezil (Aricept-PFI and generics) Galantamine (Reminyl ER-JAN and generics) Rivastigmine (Exelon-NVR and generics) For the treatment of patients with a diagnosis of mild to moderate probable Alzheimer's Disease (AD) or possible

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		Alzheimer's Disease with a vascular component, with Lewy bodies, or other factors (as specified) and who meet the following criteria: a) Initial 90-day Trial An initial 90-day trial using an available ChEI is available to patients who: i. Have a diagnosis of probable or possible AD, AND ii. Are 65 years of age or older (Coverage for patients less than 65 years of age will be considered upon receipt of a written consultation from a neurologist, psychiatrist or geriatrician supporting the diagnosis and treatment), AND iii. Have not previously used a ChEI, AND iv. Have a Mini Mental State Examination (MMSE) score of between 10 and 24. An MMSE score of 25 or 26 will be considered upon receipt of a written consultation from a neurologist, psychiatrist or geriatrician supporting the diagnosis and treatment. All MMSEs must be completed within 90-days of the request for coverage. Patients unable to tolerate the first ChEI or where their MMSE score remained between 10 and 24, but declined significantly during the trial, may also qualify for a second 90-day trial using a different ChEI. Patients must stop the first ChEI before coverage for the second 90-day trial of a ChEI will be approved. b) Continued Coverage Continued coverage of ChEIs may be available to patients who: i. Participated in a 90-day trial of a ChEI during which their MMSE score remained between 10 and 24 and either stabilized or improved, OR

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		ii. Have been previously approved for 12-months of coverage, during which their MMSE score remained above 10 and either stabilized or improved. All MMSEs must be completed within 90-days of the request for coverage. Continued coverage will not be approved for patients where their latest MMSE score is less than 10 or has dramatically decreased during the previous trial or monitoring period. Continued coverage will be approved for a maximum of twelve (12) months at a time.
Quebec	LWC	Donepezil (Aricept, Aricept RDT and generics) Galantamine (Reminyl ER and generics) Rivastigmine (Exelon and generics). As monotherapy for persons suffering from Alzheimer's disease at the mild or moderate stage. Upon the initial request, the following elements must be present: • an MMSE score of 10 to 26, or as high as 27 or 28 if there is proper justification; • medical confirmation of the degree to which the person is affected (intact domain, mildly, moderately or severely affected) in the following five domains: o intellectual function, including memory; o mood; o behaviour; o autonomy in activities of daily living (ADL) and in instrumental activities of daily living (IADL); and o social interaction, including the ability to carry on a conversation.

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		The duration of an initial authorization for treatment with donepezil is six months from the beginning of treatment. However, where the cholinesterase inhibitor is used following treatment with memantine, the concomitant use of both medications is authorized for one month. Upon subsequent requests, the physician must provide evidence of a beneficial effect confirmed by each of the following elements: • an MMSE score of 10 or more, unless there is proper justification; • a maximum decrease of 3 points in the MMSE score per six-month period compared with the previous evaluation, or a greater decrease accompanied by proper justification; • stabilization or improvement of symptoms in one or more of the following domains: o intellectual function, including memory; o mood; o behaviour; o autonomy in activities of daily living (ADL) and in instrumental activities of daily living (IADL); and o social interaction, including the ability to carry on a conversation. The maximum duration of authorization is 12 months.
Saskatchewan	LWC	(a) A diagnosis of probable Alzheimer's disease as per DSM-V criteria. (b) A mild to moderate stage of the disease with a MMSE score of 10-26 established within 60-days prior to application for coverage by a clinician. (c) A Functional Activities Questionnaire (FAQ) must be completed. (d) Patients must discontinue all drugs with anticholinergic activity at least 14 days before the MMSE and FAQ are administered. Drugs with anticholinergic activity are not to be used concurrently with rivastigmine therapy. List all current medications patient was taking at the time of assessment.

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		(e) Patients intolerant to one drug may be switched to another drug in this class. Intolerance should be observed within the first month of treatment. • Eligible patients currently taking rivastigmine would require assessment at 6 month intervals. To continue receiving rivastigmine, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results. • Eligible new patients will enter a 3 month treatment period with rivastigmine. During the 3 month trial, patients must exhibit an improvement from the initial MMSE or FAQ to continue treatment with rivastigmine. The improvement must be at least 2 MMSE points or -1 FAQ. Patients who meet these requirements will be re-evaluated at 6 month intervals. To continue receiving rivastigmine, patients must not have both a greater than 2 point reduction in MMSE and a 1 point increase in FAQ in a 6 month evaluation period. Scores are compared to the most recent test results. The MMSE score must remain at 10 or greater at all times to be eligible for coverage. • Patients who do not meet criteria to continue rivastigmine can be re-evaluated within 3 months to confirm deterioration before coverage is discontinued. • Rivastigmine does not need to be discontinued prior to MMSE or FAQ testing. • A patient intolerant of one drug and switching to a second will be considered a "new" patient and will be assessed as such. • Coverage will not be considered for patients who have failed on other drugs in this class.
Yukon	CBC	For mild or moderate Alzheimer's (with MMSE score 10-26 within previous 3 months). Reviewed on a case-by-case basis. Review after first 6 months, then yearly. Reapply with updated MMSE score each time. Only one drug approved at any time; no combination therapy. Not for patients already living in a dementia care facility.

LST – Listed as a full benefit in the formulary; **LWC** – A restricted benefit for which coverage criteria are published (e.g., exception drug status, limited use benefit, special authorization with published criteria);
LSM – list in similar manner as other drugs in class or group; NL – CEDAC Recommendation that drug be not listed; **NLT** – Reviewed by drug plan and decision is not to list; **UR** – Under review; **CBC** – Not listed as a benefit but covered on a case-by-case basis – e.g., Section 8 in Ontario or Special authorization in MB;
EXC – Excluded (belongs to category of drugs that the drug plan excludes on basis of policy or mandate – e.g., fertility agents); **APA** – Covered by another program or agency (e.g., Cancer Boards, HIV/AIDS program);
NS – No Submission received.