

Bulletin #575

September 3, 2003

DRUGS FOR THE TREATMENT OF ALZHEIMER'S DISEASE

Effective September 1, 2003, drugs used to treat Alzheimer's disease (AD) have been added as restricted benefits for beneficiaries of the New Brunswick Prescription Drug Program (NBPDP). The three cholinesterase inhibitors (ChEIs) currently on the market, Aricept[®] (donepezil), Exelon[®] (rivastigmine) and Reminyl[®] (galantamine), have been added to the NBPDP Formulary under special authorization.

The recommendation to add the ChEIs as restricted benefits was made by the Atlantic Expert Advisory Committee. The Committee also recommended that the drugs be part of a comprehensive strategy around the management of AD and that the strategy include both an education and evaluation component.

The coverage criteria for the ChEIs are included with this Bulletin. The objective of the criteria is to provide ChEIs to patients in the mild to moderate stages of AD, when they are most likely to benefit from them; and at the same time, prevent the long-term use of these drugs when they no longer make a difference in the life of a patient with AD.

Education Component

The Office of Continuing Medical Education at Dalhousie University is currently developing an educational program on the diagnosis and management of AD. This program will specifically respond to the learning needs identified in the May 2002 "Physician Needs Assessment in Alzheimer Disease and Other Dementias"¹. The education program will be case-based and will include the following:

- Identifying patients with dementia;

- Determining the type and severity of dementia;
- Assessing mental status with the Mini-Mental State Examination (MMSE);
- Assessing function with the Functional Assessment of Stage (FAST);
- Identifying target symptoms to determine response to treatment;
- Prescribing ChEIs; and
- Completing special authorization forms to ensure patients in the mild to moderate stages receive coverage.

The educational workshops, which will be approximately three hours in length, will be available to physicians by January 2004.

Criteria for Coverage of ChEIs

To be eligible for coverage, patients must meet specific clinical criteria. The criteria include:

- A MMSE² score within a specified range;
- A FAST³ score within a specified range; and
- Identifying three symptoms that will be managed with the ChEI.

The MMSE and FAST are standard measures used to assess and stage AD. These measures, along with others, have been used in clinical trials to measure

treatment effect. Unfortunately, these measures do not adequately describe effects in terms of clinical meaningfulness and relevance to the everyday lives of patients and caregivers. A method that has been used to evaluate clinically meaningful changes following the initiation of a ChEI involves identifying the problematic symptoms (or target symptoms) associated with AD in that patient and monitoring whether these symptoms improve, deteriorate or stabilize over time. Target symptoms generally fit into one of four domains:

- Cognition
- Function
- Behaviour
- Social/leisure

When target symptoms are identified, they must be observable and measurable so they can be monitored throughout the course of therapy. An example of a target symptom in the domain of behaviour is: *“Patient has become insensitive towards others and is disinhibited.”* An example of a target symptom in the domain of social/leisure is: *“Patient has lost interest in playing cards with her friends.”*

Request Forms

Specific forms have been developed to apply for coverage of ChEIs. Two request forms are attached and available on the NBPDP website www.gnb.ca/0051/0212/index-e.asp

Form # 1 is used to initiate therapy for a ChEI-naive patient. It is also used to continue therapy for a patient already taking a ChEI on September 1, 2003.

Form # 2 is used to initiate therapy of a second ChEI for a patient who has previously taken no more than one other ChEI. Note that a patient must discontinue the first ChEI before a second ChEI will be approved.

Forms are to be completed by physicians and faxed to the NBPDP Special Authorization Unit as per the usual process. Initial requests that meet the coverage criteria will be approved for a 90-day period. Well before the end of the initial 90-day period, physicians will be sent a form to complete to continue coverage for a second 90-day period. This form will provide physicians with the target symptoms initially established and will ask physicians to determine whether the symptoms have improved, stabilized or deteriorated. Patients who have stabilized or improved in at least one target symptom will be approved for a second 90 day period.

Thereafter, physicians will be sent a form to complete to continue coverage for six-month periods. The criteria to continue coverage for six-month periods are provided with this Bulletin. Note that the maximum period for which coverage will be provided is six months.

Due to the number of requests expected at this time, a delay in the initial approval of these drugs should be anticipated.

If you have any questions, please contact our office at 1-800-332-3691.

¹ This needs assessment was conducted by the Office of Continuing Medical Education at Dalhousie University for the Action Committee on Physician Diagnosis and Management of Alzheimer Disease of the Alzheimer Society of Nova Scotia.

² The MMSE refers to the MMSE with standard instruction from the Canadian Study on Health and Aging which is described in: K. Rockwood, C. MacKnight. *Understanding Dementia: A Primer of Diagnosis and Management*. Halifax: Pottersfield Press. 2001 ISBN: 1-895900-38-8.

³ The FAST refers to the FAST © 1984 by Barry Reisburg, M.D. which can be accessed at <http://www.geriatric-resources.com/html/fast.html>

SPECIAL AUTHORIZATION ADDITIONS

Drugs for the Treatment of Alzheimer's Disease

Donepezil
(*Aricept*[®])
5mg and 10mg Tablets

Galantamine
(*Reminyl*[®])
4mg, 8mg, 12mg Tablets

Rivastigmine
(*Exelon*[®])
1.5mg, 3mg, 4.5mg, 6mg
Capsules
2mg/mL Oral Liquid

1. To initiate therapy for a cholinesterase inhibitor (ChEI)-naive patient or to continue therapy for a patient already taking a ChEI on September 1, 2003:

Requests must be submitted on the appropriate NBPDP special authorization form. Patients who meet all of the following reimbursement criteria will be approved for an initial 90 days of therapy:

- a diagnosis of probable Alzheimer's disease or possible Alzheimer's disease with vascular component or Lewy bodies;
- a MMSE score of 10 to 30;
- a FAST score of 4 to 5; and
- target symptoms established in each of three domains (chosen from the four domains of cognition, function, behaviour and social/leisure).

To continue therapy for a second 90-day period:

Requests must be submitted on the appropriate NBPDP special authorization form. Patients who meet the following monitoring criteria will be approved for a second 90 days of therapy:

- stabilization or improvement in at least one target symptom.

To continue therapy for 6-month periods:

Requests must be submitted on the appropriate NBPDP special authorization form. Patients who meet the following monitoring criteria will be approved for 6 month periods of therapy:

- a MMSE score of 10 to 30 (Note: A MMSE score must be provided 6 months after starting a ChEI and then only annually thereafter.);
 - a FAST score of 4 to 5 (Note: A FAST score must be provided 6 months after starting a ChEI and then only annually thereafter.); and
 - stabilization or improvement in at least one target symptom.
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SPECIAL AUTHORIZATION ADDITIONS

Drugs for the Treatment of Alzheimer's Disease - Continued

Donepezil

(*Aricept*[®])

5mg and 10mg Tablets

Galantamine

(*Reminyl*[®])

4mg, 8mg, 12mg Tablets

Rivastigmine

(*Exelon*[®])

1.5mg, 3mg, 4.5mg, 6mg

Capsules

2mg/mL Oral Liquid

2. To initiate therapy for a patient who has previously taken no more than one other ChEI:

Requests must be submitted on the appropriate NBPDP special authorization form.

Patients will be approved for an initial 90 days of therapy with a second ChEI when the following information is provided:

- the reason for discontinuing the first ChEI; and
- any changes in target symptoms.

To continue therapy for a second 90-day period:

Requests must be submitted on the appropriate NBPDP special authorization form. Patients who meet the following monitoring criteria will be approved for a second 90 days of therapy:

3. stabilization or improvement in at least one target symptom.

To continue therapy for 6-month periods:

Requests must be submitted on the appropriate NBPDP special authorization form. Patients who meet the following monitoring criteria will be approved for 6 month periods of therapy:

- a MMSE score of 10 to 30 (Note: A MMSE score must be provided 6 months after starting a ChEI and then only annually thereafter.);
 - a FAST score of 4 to 5 (Note: A FAST score must be provided 6 months after starting a ChEI and then only annually thereafter.); and
 - stabilization or improvement in at least one target symptom.
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New Brunswick Prescription Drug Program

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Special Authorization Request for a Cholinesterase Inhibitor
Request for Initial 90 Days of First Cholinesterase Inhibitor



Please provide the following to support your request for insured coverage of the first cholinesterase inhibitor for an initial period of 90 days.

PATIENT INFORMATION			
PATIENT SURNAME	PATIENT GIVEN NAME	MEDICARE NUMBER	DATE OF BIRTH
PATIENT ADDRESS			
DIAGNOSTIC INFORMATION			
The patient has a confirmed memory problem and : MMSE score: _____ FAST score: _____			
The cause of the patient's dementia is (check as appropriate):			
<input type="checkbox"/> probable Alzheimer's Disease <input type="checkbox"/> possible Alzheimer's Disease with vascular component <input type="checkbox"/> possible Alzheimer's Disease with Lewy bodies <input type="checkbox"/> possible Alzheimer's Disease with other – specify: _____			
TARGET SYMPTOMS ESTABLISHED			
List the 3 target symptoms established:			
1. _____			
2. _____			
3. _____			
CHOLINESTERASE INHIBITOR			
Has this patient been on a cholinesterase inhibitor before? <input type="checkbox"/> YES since _____ <input type="checkbox"/> NO			
Cholinesterase inhibitor requested and starting dosage:			
<input type="checkbox"/> Donepezil (Aricept [®]) Dosage: _____ mg _____ times daily <input type="checkbox"/> Galantamine (Reminyl [®]) Dosage: _____ mg _____ times daily <input type="checkbox"/> Rivastigmine (Exelon [®]) Dosage: _____ mg _____ times daily			
Check for tolerance within <u>2 weeks</u> of starting the above cholinesterase inhibitor.			
PHYSICIAN NAME & ADDRESS:		_____ PHYSICIAN SIGNATURE	
		_____ DATE	

PLEASE RETURN FORM TO:

SPECIAL AUTHORIZATION UNIT
 NEW BRUNSWICK PRESCRIPTION DRUG PROGRAM
 P.O. BOX 690
 644 MAIN STREET, MONCTON, NEW BRUNSWICK E1C 8M7
 TOLL FREE INQUIRY LINE: 1-800-332-3691
 LOCAL FAX: 506-867-4872 TOLL FREE FAX: 1-888-455-8322

New Brunswick Prescription Drug Program

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Special Authorization Request for a Cholinesterase Inhibitor
Request for Initial 90 Days of Second Cholinesterase Inhibitor



Please provide the following to support your request for insured coverage of the second cholinesterase inhibitor for an initial period of 90 days.

PATIENT INFORMATION			
PATIENT SURNAME	PATIENT GIVEN NAME	MEDICARE NUMBER	DATE OF BIRTH
PATIENT ADDRESS			
REASON FOR DISCONTINUING FIRST CHOLINESTERASE INHIBITOR			
Cholinesterase inhibitor discontinued: _____			
Reason for discontinuing:			
<input type="checkbox"/> important deterioration in target symptoms	<input type="checkbox"/> drug interactions		
<input type="checkbox"/> gastrointestinal side effects	<input type="checkbox"/> drug-disease interactions		
<input type="checkbox"/> syncope	<input type="checkbox"/> sleep disturbances		
<input type="checkbox"/> delirium			
<input type="checkbox"/> other – specify: _____			
CHOLINESTERASE INHIBITOR			
Second cholinesterase inhibitor requested and starting dosage:			
<input type="checkbox"/> Donepezil (Aricept®)	Dosage: _____ mg _____ times daily		
<input type="checkbox"/> Galantamine (Reminyl®)	Dosage: _____ mg _____ times daily		
<input type="checkbox"/> Rivastigmine (Exelon®)	Dosage: _____ mg _____ times daily		
Check for tolerance within <u>2 weeks</u> of starting the above cholinesterase inhibitor.			
TARGET SYMPTOMS ESTABLISHED			
If new target symptoms are established, please specify:			
1. _____			
2. _____			
3. _____			
PHYSICIAN NAME & ADDRESS:		PHYSICIAN SIGNATURE _____	
		DATE _____	

PLEASE RETURN FORM TO:

SPECIAL AUTHORIZATION UNIT
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