

Bulletin # 761

August 27, 2009

## **CHOLINESTERASE INHIBITORS (ChEIs) Special Authorization Criteria and Process**

This bulletin is to advise of changes to the special authorization criteria and process for reimbursement of cholinesterase inhibitors under the New Brunswick Prescription Drug Program (NBPDP) Formulary. These changes will be effective August 27, 2009.

### **Included in this bulletin:**

- **Background information**
- **Revised special authorization criteria for coverage**
- **Frequently asked questions**

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Yours truly,



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New Brunswick Prescription Drug Program

## CHOLINESTERASE INHIBITORS (ChEIs)

### Introduction and Background

In September 2003, the New Brunswick Prescription Drug Program (NBPDP) listed three cholinesterase inhibitors (ChEIs) as special authorization benefits: donepezil (Aricept<sup>®</sup>), galantamine (Reminyl<sup>®</sup> ER) and rivastigmine (Exelon<sup>®</sup> and generics).

Between September 1, 2003 and July 31, 2009 more than 3,375 NBPDP beneficiaries had claims for at least one of the cholinesterase inhibitors (ChEIs). Total NBPDP expenditures for the ChEIs in this same time period amounted to over \$10 million.

### Changes to Special Authorization Criteria

Since the special authorization process for cholinesterase inhibitors was implemented, several modifications have been made to facilitate requests and renewals. NBPDP automatically sends renewal forms to physicians prior to the renewal date, the forms were simplified and supplementary information on target symptoms and functional assessment tests were provided.

A review of the process has identified further changes to improve the administrative process while ensuring that reimbursement is provided to appropriate patients with Alzheimer's disease.

#### ***The following changes are effective immediately:***

##### Approval times

- Approval periods for first and second requests for patients who have not previously taken a ChEI have been increased to 6 months;
- Requests submitted after the second 6 month approval will be considered for a one year approval;
- The approval period for the initial request for patients who have previously taken a ChEI and switch to another in the class has been increased to 6 months;
- Subsequent requests for patients switching ChEIs may be considered for a one year approval.

##### SA request forms

- The number of forms has been reduced from five to three;
- Forms used to make a first request for ChEI therapy (NBAD-1) and to switch to another agent (NBAD-2) are available on the NBPDP web site at <http://www.gnb.ca/0212/alzheimers-e.asp>;
- Forms used to request renewals (NBAD-3) are automatically sent to the physician three months prior to the required date.

**CHOLINESTERASE INHIBITORS (Donepezil, Galantamine, Rivastigmine)**  
**Revised Criteria for Coverage**  
**Effective August 27, 2009**

**- For the treatment of mild to moderate Alzheimer's disease**

<p><b>To initiate therapy:</b>          Requests must be submitted on the appropriate NBPDP special authorization form.  <a href="http://www.gnb.ca/0212/alzheimers-e.asp">http://www.gnb.ca/0212/alzheimers-e.asp</a></p>	
<p><b>For a patient being started on a first cholinesterase inhibitor (ChEI):</b></p>	<p>Patients who meet all of the following reimbursement criteria will be approved for <u>an initial 6 months</u> of therapy:</p> <ul style="list-style-type: none"> <li>• a diagnosis of probable Alzheimer's disease or possible Alzheimer's disease with vascular component or Lewy bodies;</li> <li>• a Mini Mental Score Exam (MMSE) score of 10 to 30;</li> <li>• a Functional Assessment &amp; Staging Test (FAST) score of 4 to 5; and</li> <li>• target symptoms established in each of three domains (chosen from the four domains of cognition, function, behaviour and social/leisure)</li> </ul>
<p><b>For a patient who has previously taken no more than one other ChEI and is switching:</b></p>	<p>Patients will be approved for <u>an initial 6 months</u> of therapy with a <u>second ChEI</u> when the following information is provided:</p> <ul style="list-style-type: none"> <li>• the reason for discontinuing the first ChEI;</li> <li>• and any new target symptoms</li> </ul>
<p><b>To continue therapy for a second 6 month period:</b></p> <p>Patients who meet the following monitoring criteria will be approved for <u>a second 6 months</u> of therapy:</p> <ul style="list-style-type: none"> <li>• a MMSE score of 10 to 30;</li> <li>• a FAST score of 4 to 5; and</li> <li>• stabilization or improvement in at least one target symptom.</li> </ul> <p>(Requests must be submitted on the appropriate NBPDP special authorization form which is automatically sent to the physician.)</p>	
<p><b>To continue therapy for 1 year period (once initial and second 6 month approvals have been completed):</b></p> <p>Patients who meet the following monitoring criteria will be approved for <u>1 year periods</u> of therapy:</p> <ul style="list-style-type: none"> <li>• 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.);</li> <li>• 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</li> <li>• stabilization or improvement in at least one target symptom.</li> </ul> <p>(Requests must be submitted on the appropriate NBPDP special authorization form which is automatically sent to the physician.)</p>	

## Frequently Asked Questions about the Cholinesterase Inhibitors (ChEIs)

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NBPDP regularly receives questions related to the coverage criteria for the ChEIs. Answers to some of the most frequently asked questions are provided below.

### 1. What was the advisory committee's rationale in recommending the ChEI criteria?

The recommendation to add the cholinesterase inhibitors as special authorization benefits was made by the Atlantic Expert Advisory Committee as part of the Atlantic Common Drug Review process. The objective of the criteria is to ensure coverage of ChEIs is provided to patients who are in the mild to moderate stages of the disease and who would benefit from drug therapy. The criteria are also intended to prevent the long term use of these drugs when they no longer make a difference in a patient's life.

### 2. What is a FAST score and why do I need to complete one for each patient?

The Functional Assessment and Staging Tool (FAST) score is a measure of a patient's functional ability.

Patients with mild Alzheimer's disease may demonstrate problems with recent memory, which impairs their ability to manage their instrumental activities of daily living (IADLs). These patients may still be quite capable of managing their own basic activities of daily living (ADLs). This would be associated with a FAST of 4.

Patients with moderate Alzheimer's disease will have more difficulty with their IADLs and may require cueing to manage their basic ADLs (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.

FAST Stage	IADL	ADL
	Managing money and meds, shopping, cooking, driving, housekeeping, using phone. (Impairment of these activities requires some community or family support, but often the patient can be left alone for much of the day.)	Feeding, toileting, dressing washing, mobility. (Impairment of these activities leads to need for frequent personal nursing care.)
4	Needs assistance	Independent
5	Needs assistance or dependent	Needs cueing or minimal assistance
6	Dependent	Dependent

The table above outlines the relationship between the FAST score and the patient's abilities with respect to instrumental activities of daily living and basic ADLs.

It is important to note that 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.

**3. Once I have a MMSE and FAST score for a patient, do I have to re-do them, or can I use the same scores on future forms?**

NBPDP requires a MMSE and FAST score at the time the ChEI is initially requested. Both tests must be repeated and the new scores submitted to NBPDP to continue coverage at 6 months and 1 year. As a guideline, MMSE or FAST scores that are more than 2 months old should not be submitted.

**4. What are some examples of reasonable target symptoms that I may want to consider in my patient?**

The following lists outline sample target symptoms in each of the four domains. The use of target symptoms such as these will assist in monitoring patients over time. How a target symptom responds to therapy is an important clue to whether the ChEI is really helping the patient. As well, target symptoms should be clinically important to that patient and their caregiver in order to provide the best monitoring tool.

**Cognition:**

- The patient may have difficulty
- Following a conversation with others
  - Following a recipe or instructions
  - Working the remote control (men)
  - Dialing a phone (familiar number)
  - Remembering children and or grandchildren's names
  - Remembering important events of past week

**Function:**

- The patient may have difficulty
- Doing own banking (machine or otherwise)
  - Preparing a meal
  - Grooming and dressing independently
  - Bathing/showering independently
  - Doing light house work independently
- (OR any Instrumental Activities of Daily Living)

### **Behaviour:**

The patient may

- Be irritable more than once daily
- Have difficulty participating in daily conversations
- Have delusions or hallucinations
- Have fluctuations in memory impairment

### **Leisure/Social:**

The patient may have difficulty

- Participating in past hobbies (e.g. card games, woodworking)
- Participating in social gatherings (e.g. hiding in a corner)
- Reading and enjoying a novel
- Enjoying gardening, watching T.V.
- Walking independently or taking dog for walk by self

### **5. I am told that target symptoms such as 'no longer able to drive' or 'decreased memory' are not good targets. What is wrong with these targets?**

Target symptoms should be measurable over time to determine whether they stabilize, improve, or deteriorate with therapy. A negative target symptom, or a target symptom describing the absence of an ability such as 'no longer able to drive,' will not provide a benchmark against which function can be compared.

### **6. Do I need to identify three different target symptoms from three of four domains?**

Ideally, identifying target symptoms from three different domains gives the broadest overview of a patient's progress over time. However, in some cases target symptoms may only be identifiable from one domain. If this is the case, three target symptoms from the relevant domain should be provided.

### **7. Can I change a patient's target symptoms and if so, when is it appropriate?**

Target symptoms should be changed whenever a new ChEI is being started. They should also be reviewed annually. This is an appropriate time to see if they should be reset. Generally, target symptoms will remain valid for at least a year.

### **8. What are the available strengths and prices of the ChEIs?**

Note: ChEIs are "flat priced", therefore the tablet strength prescribed will affect the cost of the dose. For example, using Aricept<sup>®</sup> 2 x 5mg once daily instead of Aricept<sup>®</sup> 10mg once daily doubles the daily cost of treatment.