Understanding Drug Coverage in New Brunswick

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COI Disclaimer

Consultant for Therapeutic Research Institute Canadian Prescribers' Letter and Canadian
 Pharmacists' Letter (independent advisory service,
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Learning Objectives

- Be familiar with the NB Drug Plans and know where to direct uninsured NB residents who need drug coverage
- Understand the drug review process for listing drugs on the NB Drug Plans' formulary
- Appreciate the evidence-based approach in determining criteria for drugs requiring special authorization by participating in a drug review exercise
- Recognize why some drugs require special authorization and know what information is necessary for submitting special authorization requests



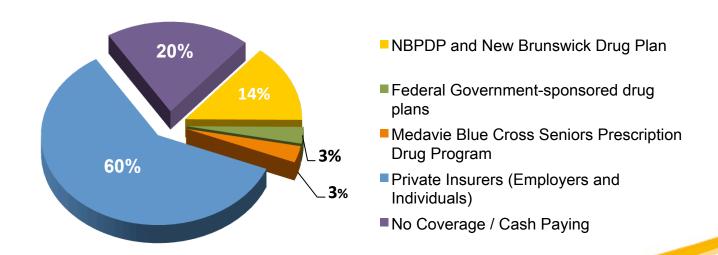
Outline

- Drug Coverage in NB
- Overview of the NB Drug Plans
 - New Brunswick Prescription Drug Program (NBPDP)
 - NB Drug Plan
- How do drugs get listed on the NB Drug Plans' formulary?
 - Evidence evaluation exercise (group discussion)
- Formulary Management
 - Special Authorization



Drug Coverage in NB

- The majority of New Brunswickers have drug coverage through private drug plans, or through publicly-funded drug programs, such as the New Brunswick Prescription Drug Program (NBPDP).
- Approximately 20% of New Brunswickers have no drug coverage, and pay for their drugs out of their own pocket. This represents approximately 70,000 families.

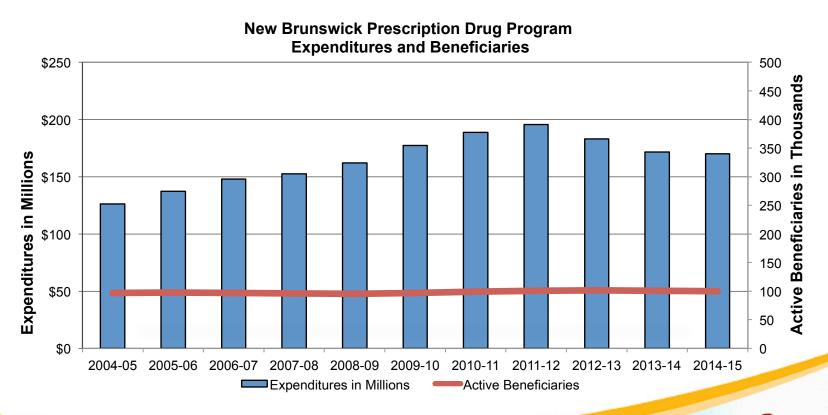




Drug Coverage in NB

Current Situation in NB – New Brunswick Prescription Drug Program (NBPDP)

In 2014-15, total NBPDP expenditures were \$170 million. Although the number of NBPDP beneficiaries has remained relatively stable over the past 10 years, costs on average have increased.





Drug Coverage Options for New Brunswickers

- Prescription Drug Coverage
 - NBPDP covers approximately 100,000 NBers including:
 - Seniors ≥ 65 who receive the Guaranteed Income Supplement (GIS) or who qualify through an income test
 - Clients of Social Development
 - Nursing Home Residents
 - Those with certain medical conditions
 - NB Drug Plan
 - Medavie Blue Cross Seniors' Prescription Drug Program



 New Brunswick Prescription Drug Program (NBPDP) Seniors (age 65 and over) who receive the Guaranteed Income Supplement (GIS) Seniors (age 65 and over) who qualify via income test 	None None	\$9.05 \$15.00	\$500 / person None
 Medavie Blue Cross Seniors' Prescription Drug Program Seniors who do not receive GIS and have incomes above NBPDP income declaration cut-off amounts 	\$1,260 (\$105/mo)	\$15.00	None
New Brunswick Prescription Drug Program (NBPDP) • Social Development (SD) clients – under 18 – 18 and older	None None	\$2.00 \$4.00	\$250 / family \$250 / family
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NBPDP Plans and Eligible Beneficiaries

Annual

Co-Pay

Ceiling

Co-pay

per Rx

Annual

Premium





What is the New Brunswick Drug Plan?

The New Brunswick Drug Plan is a prescription drug insurance plan that provides drug coverage for New Brunswickers without drug insurance. It will help New Brunswickers afford the drugs they need based on their ability to pay and coverage will not be denied because of age or pre-existing medical conditions.

Who can enrol?

Unisured New Brunswickers with a valid Medicare card can choose to enrol in the plan.

What does the plan cover?

The plan covers more than 5,000 prescription drugs, including many high cost drugs. The plan does not cover other health benefits such as vision and dental care.

How much does the plan cost?

Members pay monthly premiums to be part of the plan and pay a 30% copayment up to a maximum amount per prescription. Premiums and copayments are based on income. More information on premiums and copayments can be found on the New Brunswick Drug Plan website or can be obtained by calling the toll-free number below.

Where can I get an application form?

Application forms are available on the New Brunswick Drug Plan website or by calling the toll-free number below.

Where can I get more information?

Visit: www.gnb.ca/drugplan Toll-free: 1-855-540-7325 (Monday-Friday, 8 am – 5 pm)

E-mail: info@nbdrugs-medicamentsnb.ca





NB Drug Plan Overview

- New Brunswickers with a valid Medicare card are eligible
 - Uninsured
 - Insured
 - Individuals who need a specific drug that is not covered by their private plan, but is on the NB Drug Plan formulary
 - Individuals who have reached their annual or lifetime maximum on benefits under their private plan





NB Drug Plan Overview

- Premium (per adult) based on income. Children (18 and under) do not pay premiums but at least one parent must be enrolled
- Co-payment of 30% of prescription cost up to a maximum based on income
- No deductible
- No medical questionnaire required, no waiting period
- Currently, ~3,000 enrolled





\$17,884 or less

\$17,885 to \$22,346

\$22,347 to \$26,360

\$26,361 to \$50,000

\$50,001 to \$75,000

Over \$75,000

NB Drug Plan Overview

	Premiums Effective April 1, 2015			
Gross Income Levels	Annual	Monthly		

children

\$26,826 or less

\$26,827 to \$33,519

\$33,520 to \$49,389

\$49,390 to \$75,000

\$75,001 to \$100,000

Over \$100,000

Single with children/ **Individual** Couple with or without

Premium (per adult)

\$ 200

\$ 400

\$ 800

\$1,400

\$1,600

\$2,000

Premium (per adult)

\$ 16.67

\$ 33.33

\$ 66.67

\$ 116.67

\$ 133.33

\$ 166.67

30% Copay

to a

Maximum

per

Prescription

\$5

\$ 10

\$ 15

\$ 20

\$ 25

\$ 30

Drug Review Process

Health Canada

Assesses: Efficacy, quality and safety

Note: There is no economic evaluation (value for money)

PMBRB regulates prices for patented drug products sold in Canada

If YES, then approved for sale in Canada

Manufacturer may begin marketing product

National Common Drug Review

New drugs & indications

Assesses safety and effectiveness in conjunction with economic evaluations in comparison with current accepted therapy

Pan-Canadian Oncology Drug Review

Oncology drugs

Assesses safety and effectiveness in conjunction with economic evaluations and comparison with current accepted therapy

Atlantic Common Drug Review

- Line extensions
- Class reviews
- Older medications

Assesses safety and effectiveness in conjunction with economic evaluations and comparison with current accepted therapy

Recommendation

Decision: Provincial Governments in each of the Atlantic Provinces



NB Drug Plans Formulary

- List of drugs covered as benefits. All drugs considered for listing as benefits must be reviewed according to the standard drug review process.
- Benefit categories
 - Regular benefits
 - Restricted benefits/Special authorization (more on this later)
 - Exclusions
- Formulary on webpage
 - www.gnb.ca/0051/0212/index-e.asp



Examples
Drugs A, B, & C
all for pain
conditions





Drug A

- Head to head study vs comparator (considered appropriate)
- Similar efficacy to comparator (large trial)
- Large safety trial (> 18000 patients)
- Price lower than comparator higher than another class of drugs to treat condition



Drug B

- Head to head study vs comparator (considered appropriate)
- Comparator separated from placebo, but only the highest dose of Drug B separated from placebo
- More patients on Drug B withdrew from the study due to adverse effects than those on the comparator.
- Price higher than comparator and higher than other available drugs in its class.



Drug C

- Head to head study vs comparator (considered appropriate)
- Comparator separated from placebo, but Drug C did not separate from placebo
- High withdrawal rates, higher doses associated with greater incidence of adverse effects.
- Price higher than comparator and higher than other available drugs in its class.



Examples

- If you could only afford <u>one</u>, which one would you recommend listing?
- All were given a CDR "do not list" recommendation



Examples

What if Drug A was a COX 2 inhibitor?

- At the time, unconvincing that listing would result in savings to drug plans.
- Lumiracoxib (Prexige) first new COX-2 inhibitor brought to market after Vioxx controversy.
- August 2007: Health Canada issued an advisory that data were being reviewed.
- September 2007: FDA decision that Prexige is "not approvable".
- October 2007: Health Canada withdrew market authorization.



Drugs B and C (continued)

- Many requests and feedback from practitioners to Atlantic drug plans to list both drugs B and C
- Drugs B and C were reviewed again after generic versions became available.



Review of Evidence

- Literature search of human studies, not limited by publication year or by language; updated until review completed via alerts
- Looked for:
 - published literature
 - grey literature: regulatory agencies, HTA agencies, clinical trial registries; Internet e.g. conference abstracts
- Unpublished information
- Pharmacoeconomic evaluation



Drug B

- Superior to placebo.
- No evidence of superiority to other drugs, studies demonstrated little difference to opioids and NSAIDs.
- Dual mechanism of action and complicated metabolism make it subject to many drug interactions and serious adverse effects e.g. serotonin syndrome, increased risk of seizure.
- Even at generic price, more expensive than some comparators.
- Possible abuse potential



Drug C

- Efficacy superior to placebo.
- No evidence of superior efficacy to other drugs.
- Similar overall incidence of adverse effects.
- No pharmacokinetic drug interactions.
- Provides an alternative to existing treatments.
- Cost similar or slightly less than a comparable drug in its class, but more expensive than drugs from another class.



Drugs B and C

- Drug B not listed in any jurisdiction.
 - Tramadol
- Drug C listed in many jurisdictions (including NB), with restrictions.
 - Pregabalin



Supporting Evidence

CADTH HTA 2009:

- Reviewed drugs by category: TCAs, SNRIs, Anticonvulsants
- Included 28 studies (1437 participants) any type of neuropathic pain
- NNTs for 50% pain reduction:
 - 3.9 for TCAs
 - 4.6 for Anticonvulsants (Gabapentin and Pregabalin)
 - 5.7 for SNRIs (Duloxetine and Venlafaxine)
- Tricyclic antidepressants most effective & least expensive.



NICE Evaluation and Guideline for Neuropathic Pain

Drug	Probability (95% Crl) of pain relief after 20 weeks			Probability (95% Crl) of event within 20 weeks		
	<30%	30-49%	≥50%	Withdrawal due to AEs	Dizziness	Nausea
Placebo	0.64 (0.49,0.77)	0.13 (0.10,0.16)	0.23 (0.13,0.36)	0.09 (0.08,0.11)	0.13 (0.10,0.17)	0.10 (0.08,0.14)
Amitriptyline	0.47 (0.25,0.70)	0.15 (0.12,0.17)	0.38 (0.18,0.60)	0.24 (0.12,0.14)	0.16 (0.07,30)	0.09 (0.01,0.30)
Gabapentin	0.47 (0.28,0.66)	0.15 (0.13,0.17)	0.38 (0.21,0.57)	0.18 (0.10,0.30)	0.41 (0.24,0.63)	0.13 (0.05,0.26)
Pregabalin	0.43 (0.28,0.59)	0.16 (0.14,0.17)	0.41 (0.26,0.58)	0.19 (0.13,0.26)	0.36 (0.24,0.51)	0.12 (0.05,0.23)
Duloxetine	0.43 (0.27,0.60)	0.15 (0.14,0.17)	0.41 (0.26,0.58)	0.24 (0.13,0.40)	0.27 (0.13,0.48)	0.34 (0.20,0.53)
Tramadol	0.43 (0.22,0.65)	0.15 (0.13,0.17)	0.42 (0.21,0.64)	0.45 (0.17,0.86)	0.55 (0.2,0.94)	0.39 (0.19,0.66)

NICE Guidelines2013 http://guidance.nice.org.uk/cg173



NICE Evaluation and Guideline for Neuropathic Pain

- With cost added into the consideration:
 - Gabapentin provides one of the highest net benefit, second only to capsaicin cream.
 - The expected costs and QALYs for amitriptyline were closely comparable to those estimated for gabapentin.
 - For duloxetine and pregabalin, mean cost-per-QALY estimates from the model suggested poor value for money in comparison with amitriptyline and gabapentin.
 - Due to small numbers of patients in the included studies which were of short duration (up to 4 weeks) and higher rates of withdrawal due to AEs, tramadol should only be considered acutely as a rescue medication when awaiting referral to specialist pain services after initial treatment has failed.

NICE Guidelines2013 http://guidance.nice.org.uk/cg173



NICE Guideline for Neuropathic Pain

- Treatment for all neuropathic pain (except trigeminal neuralgia)
 - amitriptyline, gabapentin, pregabalin, or duloxetine as initial choice
 - If the initial treatment is not effective or is not tolerated, offer one of the remaining 3 drugs, and consider switching again if the second and third drugs tried are also not effective or not tolerated.
 - Consider tramadol only if acute rescue therapy is needed
 - Consider capsaicin cream for people with localised neuropathic pain who wish to avoid, or who cannot tolerate, oral treatments.



Pregabalin (Drug C) Special Authorization Criteria

SA criteria align with the evidence:

 For the treatment of neuropathic pain (e.g. diabetic peripheral neuropathy, postherpetic neuralgia) in patients who have failed a trial of a tricyclic antidepressant (e.g. amitriptyline, desipramine, imipramine, nortriptyline).





Special Authorization (SA)

- Drugs listed as special authorization benefits have specific criteria for coverage which must be met in order to be approved
- Rationale for special authorization:
 - second-line therapies
 - potential for inappropriate use
 - high cost if unrestricted, or not as cost-effective as other therapies
 - safety considerations
- SA Request Forms





NEW BRUNSWICK DRUG PLANS



NEW BRUNSWICK DRUG PLANS LONG-ACTING INSULIN ANALOGUE SPECIAL AUTHORIZATION REQUEST FORM

REQUEST INFORMATION		REQUEST INFORMATION			
oate (DDMM/YYYY):		Date (DD/MM/YYYY):			
lease select the appropriate plan: New Brunswick Drug Plan New Brunswick Drug Plan		Please select the appropriate plan: ☐ New Brunswick Prescription Drug Program ☐ New Brunswick Drug Plan			
lease complete all required sections to allow your request to be processed without delay. This form must be ompleted by a Prescriber.		Please complete all required sections to allow your request to be processed without delay. This form must be completed by a Prescriber.			
PATIENT INFORMATION		PATIENT INFORMATION			
atient's Last Name:MI:		Patient's Last Name: First Name: MI:			
lan ID or Medicare Number: Date of Birth (DD/MM/YYYY):		Plan ID or Medicare Number: Date of Birth (DD/MM/YYYY):			
treet Address:		Street Address:			
		P.O. Box: Postal Code:			
O. Box: City: Po	stal Code.	DRUG REQUESTED			
PRUG REQUESTED Prug Name / Strength / Form: Dosage Schedule:	Expected Duration of Therapy:	Drug Name / Strength / Form:	Dosage Schedule:	Patient Weight (Kg): If > 90 Kg, provide BMI:	
Diagnosis / Indication / Rationale for use: Relevant Previous Drug Therapies: Other Relevant Information:		Diagnosis / Indication / Rationale for use: Relevant Previous Drug Therapies: Other Relevant Information:	☐ Diagnosed with Type 1 or Type	nanagement.	
REQUESTOR INFORMATION		REQUESTOR INFORMATION			
lequestor Name:	PLEASE RETURN			PLEASE RETURN	
lequestor Address:	COMPLETED FORM TO: Special Authorization Unit, New Brunswick Drug Plans	Requestor Address:		COMPLETED FORM TO: Special Authorization Unit, New Brunswick Drug Plans	
icense Number (e.g. CPSNB, NANB, NBPhS, etc.):	P.O. Box 690 644 Main Street Moncton, NB E1C 8M7	License Number (e.g. CPSNB, NANB, NBPhS, etc.):		P.O. Box 690 644 Main Street Moncton, NB E1C 8M7	
ax Number:	Inquiry Line: 1-800-332-3691 Local Fax: 506-867-4872	Fax Number:		Inquiry Line: 1-800-332-3691	
equestor Signature:		Requestor Signature:		Local Fax: 506-867-4872	

Required Information on SA

Patient Identification

- Name of patient
- NB Medicare number or Drug Plan ID number
- Date of birth

Prescriber Identification

Name, address, telephone number and FAX number (if applicable) of prescriber

Drug Requested

- Drug name, strength and dosage form
- Dosage schedule
- Expected duration of therapy



Required Information on SA

Reason for the Request

- Diagnosis and/or indication for which the drug is being used
- Information regarding previous drugs which have been used and the patient's response to therapy where appropriate
- Any additional information that may assist in making a decision on the request for special authorization



Medications Not Considered under SA

- New drugs not yet reviewed by the Common Drug Review (CDR), the pan-Canadian Oncology Drug Review (p-CODR); or the Atlantic Common Drug Review (ACDR)
- Drugs excluded as eligible benefits further to the expert advisory committee's review and recommendation
- Drugs not licensed or marketed in Canada (e.g. drugs obtained through Health Canada's Special Access Program)
- Products specifically excluded as benefits as identified on the exclusion list



NB Drug Plans Formulary

Exclusions (except those specifically listed)

- Drugs not authorized for sale and use in Canada
- Over-the-counter (OTC) or non-prescription drugs, vitamins, and minerals
- Dietary or nutritional supplements and food products
- Weight loss products
- Products for the treatment of erectile/sexual dysfunction, or infertility
- Products for esthetic or cosmetic purposes
- Soaps, cleansers, shampoos, antiseptics, or disinfectants
- Drugs for the prevention of travel acquired diseases
- Diagnostic agents and point-of-care testing kits
- Medical supplies, devices and equipment (e.g. prostheses, first aid supplies, ostomy supplies, diabetes test strips and syringes, etc.)
- Vaccines



Questions?



Thank you

