The Alzheimer's Drug Therapy Initiative:

Drug Coverage with

Evidence Development

in British Columbia

Elaine Chong, British Columbia Ministry of Health

2017 CADTH Symposium

April 24, 2017

BRITISH COLUMBIA

Overview

- Background
- Utilization
- Drug Review Process
- Ministry Decision
- Challenges and Opportunities
- Discussion and Questions

Acknowledgements

- British Columbia Ministry of Health
  - Eric Lun, Jenna Peluso
  - Bob Nakagawa, Ron Mattson, Caroline Caiger, Judy Thomas
- Researchers
  - Dr. Neena Chappell, Dr. Lynn Beattie, Dr. Robin Hsiung, Dr. Colin Dormuth, Dr. Malcolm Maclure, Dr. Claudia Jacova, Dr. Philip Lee
- Clinicians
- Patients
- Alzheimer Society
- Industry: Janssen, Novartis, Pfizer

Background

- Cholinesterase inhibitor drugs
  - Donepezil (Aricept®, generics) – oral
  - Galantamine (Reminyl®, generics) – oral
  - Rivastigmine (Exelon®, generics) – oral
  - Rivastigmine (Exelon®) – transdermal patch

- Mild to moderate Alzheimer's disease

- Alzheimer's Drug Therapy Initiative (ADTI)
  - Collaboration between Ministry of Health (the Ministry), Alzheimer Society of BC, experts in dementia and geriatric care, researchers, industry, clinicians, and individuals affected by Alzheimer's disease
  - Launched in Oct 2007
  - Completion when Ministry decisions are announced

Background

- Coverage with Evidence Development (CED) approach
  - Gather additional data on safety, effectiveness, and appropriate use
  - Inform drug listing decisions on whether to add to BC PharmaCare formulary, and if so, under what criteria

- Coverage status of cholinesterase inhibitor drugs
  - During the ADTI, PharmaCare non-benefits under review
  - Temporary coverage through the ADTI (until a PharmaCare coverage decision is made)
  - Special Authority required
  - Coverage for patients in community as well as residents of extended care hospitals in the health authorities

Background

- ADTI Research (University of Victoria)
  - Seniors' Medication Study
  - Utilization and Cost Project
  - Clinical Epidemiological Project
  - Caregiver Appraisal Study

- ADTI Research (University of British Columbia)
  - Clinical Meaningfulness in Alzheimer Disease Treatment (CLIMAT)

- ADTI Education
  - Provincial Dementia Education Program (completed Dec 2012)
  - Ministry objective to increase awareness and training opportunities to support ADTI
  - Accredited dementia education to physicians, pharmacists, and other health care professionals

Drug Review Process

- Ministry used its usual drug review process to make decisions about PharmaCare coverage of the cholinesterase inhibitor drugs
  - Existing PharmaCare policies, programs, priorities and resources
  - Patient, clinician, and manufacturer input
  - Evidence-informed recommendations of the Drug Benefit Council (DBC)
  - Reports posted at: http://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/what-we-cover/drug-coverage/drugs-requiring-pre-approval/alzheimersdrugs/alzheimers-drug-therapy-review-reports
- Ministry requests to DBC
  - Should the cholinesterase inhibitors be covered by PharmaCare in the community and in the long-term care setting?
  - If supportive of coverage, are the products different, and how should coverage be provided (initiation and renewal coverage criteria)?

DBC Recommendation

- Based on the evidence provided, the Drug Benefit Council (DBC) recommends that the cholinesterase inhibitor drugs (donepezil, galantamine, and rivastigmine) should be listed for the treatment of mild to moderate Alzheimer's disease.
  - Donepezil tablets should be listed as a Limited Coverage benefit with Special Authority criteria, given that there are no significant differences between the cholinesterase inhibitors and the most cost-effective product should be prioritized;
  - Galantamine extended release capsules and rivastigmine capsules should be listed as second-line Special Authority benefits only for patients experiencing intolerance to donepezil;
  - Do not list rivastigmine patches at the current price.

Ministry Decision

- Effective April 1, 2016

- List donepezil as a first-line Limited Coverage benefit
- List galantamine and rivastigmine (oral) as second-line Limited Coverage benefits
  - Only for patients with intolerance to donepezil
  - No coverage for patients switching due to ineffectiveness (clinical failure)
- Rivastigmine patch not covered as significant price reduction was not achieved
- Existing patients continue “grandfathered” coverage (including current patch patients)

Challenges and Opportunities

Coverage with Evidence Development

one approach but not the only answer

- Real-world study design → balance scientific rigour with reality
- Study recruitment → education program, physician fee item
- Patients in residential care → partnership with health authorities
- Data management → manual data collection, dedicated data clerk
- Special Authority approvals → heavy workload, systems solutions
- Data access → collaboration and communication

DISCUSSION AND QUESTIONS

Elaine Chong, PharmD, BCPS

Director, Decision Support and Evaluation Guidance

Drug Intelligence and Optimization

Medical Beneficiary and Pharmaceutical Services Division

British Columbia Ministry of Health

elaine.chong@gov.bc.ca