D&T Decisions

... from the Drugs and Therapeutics Committee

nova scotia health authority

Central Zone

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The following policies were approved by the Medical Advisory Committee (Apr16, May16)) on the recommendation of the Drugs and Therapeutics Committee (Mar16, Apr16).

I. Additions to Formulary

Pneumococcal CONJUGATE 13-valent vaccine, *Prevnar 13*®
Meningococcal ACYW conjugate vaccine, *Menveo*®
Meningococcal B vaccine, *Bexsero*®

The Nova Scotia Department of Health and Wellness (DHW) recognizes the need to provide immunizations to individuals at high risk of acquiring vaccine preventable diseases; therefore, vaccines are publicly funded for high risk individuals including asplenic patients who are particularly susceptible to encapsulated organisms.

To facilitate the appropriate vaccination of patients post-splenectomy, the Central Zone Pharmacy Department prepares Splenectomy Vaccine Kits that include information for the Family Physician, patient education materials and one dose each of the recommended vaccines. There is a new recommendation to include the meningococcal vaccine Bexsero® to protect against meningococcal B. To align our Central Zone Formulary with current vaccination recommendations, the following vaccines that are included in the Splenectomy Vaccine Kits have been added to the Formulary [the hemophilus influenza B (Act-Hib®) vaccine is already Formulary]:

- Pneumococcal CONJUGATE 13-valent pre-filled syringe (*Prevnar 13*®)
- Meningococcal ACYW conjugate (*Menveo*®)
- Meningococcal B pre-filled syringe (*Bexsero*®)

Raltegravir, *Isentress*®
Tenofovir/ emtricitabine, *Truvada*®

A new NSHA Clinical Practice Guideline for Blood Borne Pathogen Exposure has been developed and approved by the Infectious Diseases Expert Group for NS and the Central Zone Antimicrobial Agents Subcommittee (AAS). These Guidelines reflect evidence based Canadian practice and were prepared to assist clinicians in the appropriate management of adults, children and adolescents (greater than 12 years of age) who have potential exposure to blood and other body fluids that may contain hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV). The antiretroviral post exposure prophylaxis (PEP) regimen has been revised. When PEP for HIV is appropriate, the following drug selection is recommended:

- raltegravir 400 mg po q12h
  PLUS
- Truvada® (tenofovir 300 mg + emtricitabine 200 mg)
  1 tablet po daily
  (can be taken without regards to meals) for 28 days.

The raltegravir plus Truvada® regimen is recommended as HIV PEP because of its tolerability, potency, convenient administration and association with minimal drug interactions. Additionally, although the data on the safety of raltegravir during pregnancy is limited, this regimen could be administered for PEP during pregnancy. To facilitate timely PEP initiation, “starter kits” are kept at sites expected to manage HIV PEP. The HIV PEP starter kits that are prepared for the Central Zone Emergency Department now provide a 5 day supply of raltegravir and Truvada®; therefore, these medications have been added to the Formulary.

II. Non-Formulary

Tolvaptan, *Jinarc™*

Tolvaptan (as brand name Jinarc™) is indicated to slow the progression of kidney enlargement in patients with autosomal dominant polycystic kidney disease (ADPKD). Tolvaptan is a selective vasopressin V2-receptor antagonist that inhibits the binding of vasopressin at this receptor in the kidney. Decreased binding of vasopressin at the V2-receptor causes a decrease in the secondary messenger adenosine-3', 5'-cyclic monophosphate (cAMP) resulting in a decrease in cyst cell growth in the kidneys and luminal fluid secretion into cysts.

The TEMPO 3:4 trial is the only phase 3 trial looking at tolvaptan in ADPKD. In this trial, the primary outcome of annual percent change in total kidney volume (TKV) was statistically significantly less with tolvaptan than placebo. However, TKV is a surrogate endpoint and the relationship between this finding and clinical outcomes (e.g., need for dialysis or renal replacement therapy) and the extent to which these changes are maintained over the lifetime of the patient is not known.

Study discontinuation due to adverse effects occurred in 15.4% of patients in the tolvaptan group compared to 5.0% in the placebo group. Adverse effects from diuresis (thirst, polyuria, nocturia, and pollakiuria) were more common in patients taking tolvaptan. Serious adverse events that were more common in the treatment group included alanine aminotransferase (ALT) and aspartate aminotransferase (AST) elevation, chest pain, and headache. The Health Canada approved indication for Jinarc™ states that tolvaptan is available for treatment of patients with ADPKD only through a hepatic safety monitoring and distribution program conducted and maintained by, or for, the market authorization holder of Jinarc™.

The manufacturer is also coordinating the coverage of Jinarc™ through third party insurance and compassionate means; therefore, there is no economic impact occurred by the Central Zone for Jinarc™. Outpatients may receive a prescription in clinic and the manufacturer's distribution program will supply the medication via community pharmacy.

The Canadian Drug Expert Committee (CDEC) has recommended that tolvaptan not be listed to slow the progression of kidney enlargement in patients with ADPKD and tolvaptan was not added to the Central Zone Formulary.

III. New Guidelines

Bevacizumab, *Avastin®*

Two new guidelines have been approved for bevacizumab.

A new Guideline for the role of bevacizumab in advanced ovarian cancer has been approved by the Drugs and Therapeutics Committee.

Approved Restriction:
As a first line treatment of patients with advanced stage ovarian cancer at a high risk of progression (stage III with > 1 cm residual disease, stage III unresectable or stage IV) epithelial ovarian, primary peritoneal or fallopian tube cancer and good performance status.

This would include initial treatment in combination with chemotherapy and maintenance therapy for up to 12 additional cycles or until disease progression whichever occurs first.

A new Guideline for the role of bevacizumab in metastatic cervical cancer has been approved by the Drugs and Therapeutics Committee.

Approved Restriction:
In combination with chemotherapy for patients with metastatic (stage IVB), persistent or recurrent carcinoma of the cervix of all histologic subtypes (except small cell) and good performance status.

Retreatment with bevacizumab plus chemotherapy may be offered to patients who have achieved a complete response (with previous bevacizumab and chemotherapy) and off treatment for at least 6 months.

Aldesleukin, *Proleukin*

Approved Restriction:
As a single agent for intralesional injection for patients with unresectable in-transit metastatic melanoma (i.e., patients with rapidly developing in-transit metastases after surgery or patients who present with multiple in-transit metastases unsuitable for surgical resection).

Romidepsin, *Istodax®*

Approved Restriction:
As a single agent for patients with relapsed/ refractory peripheral T-cell lymphoma (PTCL) who are ineligible for transplant and who have undergone previous systemic therapy and have an ECOG performance status (PS) of 0-2.

IV. Medication Policies

The following policies have been approved by the Medical Advisory Committee on the recommendation of the Drugs and Therapeutics Committee. These policies will be added to the Medication Policy and Procedure Manual.

CC 50-065	Peritoneal Dialysis (PD); Care of the Patient Receiving

V. IV Manual

New Monograph Documents:
EPINEPHrine 32 mcg/mL Infusion Table
Vasopressin 0.2 units/mL Infusion Table
Vasopressin 0.4 units/mL Infusion Table

Revised Monographs/ Documents:
Amiodarone 1.8 mg/mL infusion table
Amphotericin B lipid complex
ceFAZolin
Dexmedetomidine
Dexmedetomidine 4 mcg/mL infusion table
Dextrose 50%
DOPamine 1600 mcg/mL infusion table
Enalaprilat
EPINEPHrine
EPINEPHrine 16 mcg/mL infusion table (now in mcg/kg/min)
Gentamicin
Haloperidol
Infliximab
Iron SUCROSE
Isoproterenol
Isoproterenol 4 mcg/mL infusion table
Magnesium sulphate
NORepinephrine 16 mcg/mL infusion table
Pentamidine
Procainamide
Procainamide 4 mg/mL infusion table
Sodium bicarbonate
Tranexamic acid
Vasopressin

Removed Monographs/ Documents:
ChlorproMAZINE
EPINEPHrine 4 mcg/mL Infusion Table
EPINEPHrine 8 mcg/mL Infusion Table
Ferumoxytol
Heparin Infusion Table
Perphenazine
Promethazine
Vasopressin 0.1 unit/mL Infusion Table
Vasopressin 1 unit/mL Infusion Table

VI. Pre-Printed Orders

The following pre-printed orders have been approved by the Medical Advisory Committee on the recommendation of the Drugs and Therapeutics Committee.

PPO 0121	Bypass Graft Post-op Orders
PPO 0124	Post-Splenectomy Vaccinations
PPO 0353	Multiple Myeloma – VMP for Transplant Ineligible Patients (Bortezomib, Melphalan, PrediniSONE)
PPO 0433	CycloPHOSPHAMIDE Bortezomib, Dexamethasone (CyBorD) for Multiple Myeloma – Transplant Eligible Patients OR Relapse/ Refractory Disease
PPO 0457	Carotid Endarterectomy, Post-op Orders
PPO 0458	Above or Below Knee Amputation Post-op Orders
PPO 0477	Endovascular Aneurysm Repair
PPO 0521	Infliximab Infusion
PPO 0522	Blood Borne Disease Exposure
PPO 0539	High Dose Insulin for Calcium Channel Blocker or Beta Blocker Overdose – Adult

The information contained in this newsletter may also be accessed online:
http://cdhaintra/departmentservices/pharmacy/Formulary/index.cfm

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