D&T Decisions

… from the Drugs and Therapeutics Committee

Issue #67: Aug.1, 2019

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The following policies were approved by the Medical Advisory Committee (Mar19, May19, Jun19) on the recommendation of the Drugs and Therapeutics Committee (Feb19, Mar19, Apr19, Jun19).

I. Additions to Hospital Formulary

Insulin glargine, *Basaglar™*

Basaglar (insulin glargine) is a biosimilar with the reference product Lantus (insulin glargine). Biologics are medications made from the cells of living organisms that cannot be exactly replicated; therefore, biosimilars are considered alternatives to, but not generics of their reference product and are not considered interchangeable.

Basaglar and Lantus are long-acting recombinant human insulin analogues with identical amino acid sequences. Basaglar is less expensive than Lantus and is a full benefit on the NS Provincial Drug Plan Formulary (i.e., Pharmacare) while Lantus remains restricted with criteria. There are two Phase III randomized trials (one open-label and one double blind) comparing Basaglar to Lantus that demonstrated non-inferiority. Basaglar has been added to the NSHA Hospital Formulary (no restrictions) and Lantus remains on the Hospital Formulary with restrictions.

Ursodiol, *URSO®*

Ursodiol is approved by Health Canada for the management of cholestatic liver diseases, such as primary biliary cirrhosis. Ursodiol is a hydrophilic bile acid preparation that is present in low concentrations in normal bile. Use of oral ursodiol increases the proportion of hydrophilic bile acids replacing and altering toxic concentrations of hydrophobic bile acids that can cause hepatocellular injury.

Veno-occlusive disease (VOD), also referred to as hepatic sinusoidal obstruction syndrome, is a feared major complication of allogenic and autologous hematopoietic stem cell transplantation (HSCT). It is characterized by hyperbilirubinemia, upper right quadrant pain, hepatomegaly, jaundice and ascites, edema or weight gain. Symptoms most often occur three to four weeks post-transplant. Although estimates vary, VOD is thought to affect 14% of patients undergoing HSCT with a mortality rate upward of 80% in severe cases. VOD pathogenesis is incompletely understood but is thought to result from hepatic sinusoidal endothelial cell dysfunction.

A 2015 Cochrane review of four studies of ursodiol versus placebo/ nothing/ heparin alone showed a statistically significant decrease in incidence of VOD and mortality attributable to hepatic VOD with no evidence for either endpoint when comparing IV unfractionated heparin (UFH) to placebo. There was no difference in overall survival. Various guidelines for diagnosis and management of VOD following HSCT recommend ursodiol for VOD prophylaxis. Heparin is not recommended for VOD prophylaxis because of an increased risk of toxicity. Due to the significant morbidity and mortality of VOD, routine prophylactic therapy to prevent VOD in transplant recipients is common and ursodiol is a preferred option.

Icatibant, *Firazyr®*

Icatibant is a bradykinin receptor blocker that is indicated to treat patients with hereditary angioedema (HAE). There is an absence or dysfunction of C-1 esterase-inhibitor in HAE that indirectly leads to an overproduction of bradykinin. Bradykinin is a vasodilator and

the key mediator of the inflammatory processes that lead to swelling and pain in a HAE attack. Icatibant is a competitive antagonist for the bradykinin 2 receptor; therefore, icatibant occupies the receptor and bradykinin binding is blocked reducing the severity of a HAE attack.

A multicenter, randomized, double blind, placebo controlled trial (FAST-3) of subjects presenting within 12 hours of onset of the HAE attack found that treatment with icatibant 30 mg subcutaneous injection (compared to placebo) resulted in a statistically significantly shorter time to onset of symptom relief and a statistically significant shorter time to initial symptom improvement in non-laryngeal attacks. Additionally, fewer patients treated with icatibant required rescue medication. Although the study failed to find a statistically significant difference in laryngeal attacks, the small sample size may have precluded a meaningful comparison. No drug-related serious adverse events or deaths were reported in subjects receiving icatibant. Commonly reported adverse events were headache, sinusitis, nausea, diarrhea and injection site reactions.

Approved Restriction
For the treatment of acute attacks of confirmed or suspected hereditary angioedema (HAE) under the following conditions:

- treatment of non-laryngeal attacks of at least moderate severity, or
- treatment of acute laryngeal attacks

Vernakalant, *Brinavess™*

Vernakalant is an intravenous antiarrhythmic approved by Health Canada for the rapid conversion of recent onset atrial fibrillation (AF) to sinus rhythm, specifically for non-surgery patients, with duration of AF ≤ 7 days and post-cardiac surgery patients, with duration of AF ≤ 3 days. Vernakalant is an atrial-selective antiarrhythmic drug that prolongs the atrial refractory period with minimal effects on ventricular repolarization. Since vernakalant has a quick onset of action and short half-life, it could potentially facilitate earlier discharge compared to currently available antiarrhymic options.

Atrial fibrillation (AF) is described as an irregularly irregular rhythm involving uncoordinated atrial contraction. It is one of the most common cardiac arrhythmias and its incidence increases with age. AF is often associated with various forms of structural heart disease (e.g., myocardial ischemia or infarction, hypertensive heart disease, valvular disorders) and is a common complication following cardiac surgery. Patients experiencing AF have a significantly increased risk of thromboembolism and stroke.

Vernakalant has been evaluated and demonstrated efficacy as a first line agent for restoration of normal sinus rhythm (NSR) in patients with acute onset AF less than or equal to seven days, and AF of less than or equal to three days following cardiac surgery. Specifically, when compared to ibutilide and amiodarone its use resulted in shorter time to conversion to NSR and greater proportion of patients in NSR within 90 minutes. Although limited data exists for its efficacy in comparison to established therapies for post-surgery arrhythmias, it has demonstrated positive results in comparison to placebo and as part of a treatment protocol with flecainide and electrical cardioversion.

Vernakalant is generally well-tolerated and safe; however, some patients have experienced serious adverse effects and there are many contraindications to its use. The most common adverse effects associated with vernakalant include dysgeusia, sneezing, paresthesia and nausea. Hypotension may occur and although this effect is often transient and usually resolves without intervention, a small portion of patients in clinical trials required fluids and/or norepinephrine.

Approved Restriction
For use in the CZ QEII Cardiology Electrophysiology (EP) lab.

Dornase Alfa, *Pulmozyme®*

Dornase alfa is a recombinant human deoxyribonuclease (DNase) produced in Chinese hamster ovary cells that acts as a mucolytic agent. In cystic fibrosis (CF), it is administered as an inhaled medication to reduce sputum viscosity (by the cleavage of free DNA from degenerating leucocytes) which aids sputum clearance. Dornase alfa is Health Canada approved, along with standard therapy, for the reduction of respiratory infections and for the improvement of lung function (e.g., FEV1) in CF patients. The 2013 Cystic Fibrosis Pulmonary Guidelines by the American Journal of Respiratory and Critical Care Medicine recommends dornase alfa for individuals with mild, moderate, and severe lung disease. Based upon individual trials that consistently show improvements in lung function (e.g., FEV1) and reductions in rates of exacerbations, dornase alfa is recommended for daily use in patients 6 years of age and older.

Intrapleural administration of dornase alfa is used off-label in conjunction with fibrinolytic therapy for the treatment of pleural effusion. Standard therapy for pleural infection includes chest tube placement, fluid drainage and antibiotic treatment; however, treatment failure occurs in about one third of patients and requires surgical drainage. Pleural infections cause increased length of hospital stay and carry a mortality rate of 10 to 20%. Fibrinolytic therapy (e.g., streptokinase, alteplase/ tPA) is proposed to dissolve intrapleural fibrinous septations and there have been case reports of successful treatment of pleural infection with tPA when combined with dornase alfa. As with CF, degenerating leucocytes are present in high concentrations within infected pleural fluid. The cleavage of free DNA is thought to decrease fluid viscosity; therefore, treatment with dornase alfa promotes fluid drainage and clearance of the infection.

A multicenter, randomized, double blind, placebo controlled trial (MIST-2) is the largest trial supporting the use of dornase alfa for pleural effusion. Compared to placebo, the t-PA-dornase alfa group had a greater percentage change from baseline in the area occupied by effusion and surgical referral occurred in 2 of 48 patients in the t-PA-dornase alfa group versus 8 of 51 in the placebo group. Average duration of hospital stay in days from the date of randomization was reported as 11.8 ± 9.4 versus 24.8 ± 56.1 (t-PA-dornase versus placebo).

Ivabradine, *Lancora™*

Ivabradine is an I_f inhibitor approved for the treatment of stable chronic heart failure that is intended as an add-on therapy to stable background and optimized guideline directed medical therapy. Ivabradine works solely by decreasing heart rate and has no effect on blood pressure or myocardial contractility. It requires the

patient to be in normal sinus rhythm because it selectively inhibits the I_f in the sinus node which prolongs the slow depolarization phase.

Heart rate reduction is a guideline directed and evidence based therapeutic target for the treatment of heart failure with reduced ejection fraction. Beta blockers are a mainstay of heart failure treatment but have been shown to be underused and under-optimized which may be attributed to difficulties in initiating and up titrating as well as contraindications and poor tolerability to this class of drugs. The 2017 CCS Heart Failure Guidelines recommend that every effort should be made to maximize beta blocker therapy before initiation of ivabradine but that the drug should be considered in those that remain symptomatic despite optimized guideline directed medical therapy for heart failure in patients with a resting HR >70 bpm, are in normal sinus rhythm and have had a previous heart failure hospitalization within the previous 12 months.

A randomized, double blind, placebo controlled trial (SHIFT) evaluated the effect of ivabradine on the composite primary endpoint of cardiovascular (CV) death and heart failure admission. The reduction in the primary outcome was largely driven by hospital admissions for worsening heart failure and there was no statistically significant decrease in the CV death component. The Health Canada indication is based on data from a subgroup analysis that showed both CV death and HF hospitalization contributing to the treatment effect; however, hospitalization remained the main driving component. In the subgroup of patients with a baseline resting heart rate of <77 bpm, the primary composite endpoint did not reach statistical significance.

Ivabradine adverse effects include symptomatic and asymptomatic bradycardia, visual side effects (phosphenes) and atrial fibrillation. Ivabradine is a cytochrome P450-3A4 substrate; therefore, there are potential drug interactions if used concurrently with CYP3A4 inducers or inhibitors (i.e., ivabradine drug levels may lower or increase).

Approved Restriction
For the treatment of adult patients with NYHA classes II or III stable chronic heart failure, administered in combination with standard chronic heart failure therapies, who meet all of the following criteria:

- reduced LVEF (<35%)
- sinus rhythm with a resting heart rate ≥77 beats per minute
- at least one hospitalization due to heart failure in the past year
- NYHA class II to III symptoms despite at least four weeks of optimal treatment of the following:
  - a stable dose of an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptorblocker (ARB); **and**
  - a stable dose of a beta blocker; **and**
  - an aldosterone antagonist

Ulipristal, *Ella™*

Ella™ brand ulipristal (30 mg tablet) is approved as an emergency contraceptive for the prevention of pregnancy when taken within 120 hours (5 days) of unprotected intercourse or a known or suspected contraceptive failure. Ulipristal is a selective progesterone receptor modulator with primarily antiprogestin activity that can delay ovulation by as much as five days. Current NSHA Hospital Formulary emergency contraceptive medications include levonorgestrel 1.5 mg (Plan B®) and ethinyl estradiol 0.05 mg/ levonorgestrel 0.25 mg combination tablet (Ovral®) used for the Yuzpe regimen.

Potential candidates for emergency contraception (EC) include women who have had recent unprotected intercourse (including sexual assault victims seen in Emergency Departments), recent failure of another method of contraception and those who do not desire pregnancy. Plan B® is only indicated up to 72 hours after unprotected intercourse and there is evidence that ulipristal is more effective than Plan B® when used in women with BMI >25.

The most common adverse reactions of ulipristal EC are headache, nausea, abdominal pain, dysmenorrhea, fatigue and dizziness. Patients can also have a delayed return of menses after use. Ulipristal is a substrate of cytochrome P450-3A4 and could be affected by drugs that induce or inhibit CPY3A4 metabolism pathways resulting in decreased effectiveness or increased exposure. Contraceptive action of combined hormonal contraceptives and progestogen-only contraception may be reduced because ulipristal binds the progesterone receptor with high affinity.

Approved Restriction
Patients presenting >72 hours to <120 hours after unprotected intercourse/ contraceptive failure or patients with BMI >25.

Inhaler Devices:

Indacaterol, *Onbrez® Breezhaler®*
Aclidinium, *Tudorza® Genuair®*
Glycopyrronium, *Seebri® Breezhaler®*
Umeclidinium, *Incruse Ellipta*
Fluticasone furoate, *Arnuity Ellipta*
Mometasone, *Asmanex® Twisthaler®*
Aclidinium + formoterol, *Duaklir® Genuair®*
Indacaterol + Glycopyrronium, *Ultibro® Breezhaler®*
Tiotropium + olodaterol, *Inspiolto™ Respimat®*
Umeclidinium + vilanterol, *Anoro Ellipta*
Fluticasone + vilanterol, *Breo Ellipta*
Mometasone + formoterol, *Zenhale® MDI*

The NSHA Hospital Formulary has been aligned with the NS Provincial Drug Plan Formulary (i.e., Pharmacare) with regards to listed inhaled medications and their associated inhaler devices. Patients with chronic obstructive lung diseases (COPD, asthma) are frequently hospitalized and this provides an opportunity to start patients on appropriate maintenance inhaled therapies and/ or continue the treatments that they are already using at home. Since inhaled medications each have a unique inhaler device, hospitalization is an opportunity to assess and teach patients proper inhaler technique.

Inhaled medications can be categorized as short acting beta2 agonists (SABA), long acting beta2 agonists (LABA), short acting

muscarinic antagonists (SAMA), long acting muscarinic antagonists (LAMA) and inhaled corticosteroids (ICS). These medications are available as single entity and combination inhaler devices. There are several new inhalation devices available on the market (e.g., Respimat, Breezhaler, Ellipta, Genuair) and many older devices are still available [e.g., Metered Dose Inhalers (MDI), Turbohalers, Diskus, Handihaler]. Each device has unique characteristics and advantages depending on a patient's clinical condition, lung function capacity and physical ability; therefore, patient assessment and teaching is essential to ensure appropriate medication delivery by the inhalation route.

To align Formularies, the following inhaler devices have been added to the NSHA Hospital Formulary: indacaterol (Onbrez® Breezhaler®), aclidinium (Tudorza® Genuair®), glycopyrronium (Seebri® Breezhaler®), umeclidinium (Incruse Ellipta), fluticasone furoate (Arnuity Ellipta), mometasone (Asmanex® Twisthaler®), aclidinium + formoterol (Duaklir® Genuair®), indacaterol + glycopyrronium (Ultibro® Breezhaler®), tiotropium + olodaterol (Inspiolto™ Respimat®), umeclidinium + vilanterol, (Anoro Ellipta), fluticasone + vilanterol (Breo Ellipta), mometasone + formoterol (Zenhale® MDI).

The NSHA Hospital Formulary restrictions will also align with the Exception Status Drug Criteria of the NS Provincial Drug Plan Formulary (i.e., Pharmacare). The NS Provincial Formulary criteria, forms and notes for coverage may be found on the website:
https://novascotia.ca/dhw/pharmacare/formulary.asp

II. New Guidelines

Carfilzomib, *Kyprolis*®

Two new guidelines have been approved for carfilzomib.

A new guideline for the role of carfilzomib in combination with dexamethasone for patients with relapsed multiple myeloma has been approved by the Drugs and Therapeutics Committee.

Approved Restriction:
In combination with dexamethasone for patients with relapsed multiple myeloma with a good performance status who have received at least one prior treatment. Treatment with carfilzomib should continue until disease progression or unacceptable toxicity.

A new guideline for the role of carfilzomib in combination with lenalidamide and dexamethasone for patients with multiple myeloma has been approved by the Drugs and Therapeutics Committee.

Approved Restriction:
In combination with lenalidamide and dexamethasone for patients with multiple myeloma who have received at least one prior treatment. Patients must be sensitive to lenalidomide and bortezomib or not previously exposed.

If previously treated with lenalidamide patients must not have:
- Discontinued therapy because of adverse effects, OR
- Disease progression during the first 3 months of treatment, OR
- Progression at any time during treatment if lenalidamide and dexamethasone was their most recent treatment.

Treatment should be in patients who have a good performance status and are deemed to have adequate renal function.

Treatment with carfilzomib should continue until disease progression or unacceptable toxicity to a maximum of 18 cycles.

Patients are eligible for only one triplet therapy, i.e. either daratumumab or carfilzomib triplet therapy, in the relapsed/refractory setting.

Daratumumab, *Darzalex*®

Two new guidelines have been approved for daratumumab.

A new guideline for the role of daratumumab in combination with bortezomib and dexamethasone for patients with relapsed and refractory multiple myeloma has been approved by the Drugs and Therapeutics Committee.

Approved Restriction:
In combination with bortezomib and dexamethasone for patients with multiple myeloma who have received at least one prior treatment. Patients must be sensitive to bortezomib or not previously exposed. Treatment should be in patients who have a good performance status. Treatment with daratumumab should continue until disease progression or unacceptable toxicity.

Patients are eligible for only one triplet therapy, i.e. either daratumumab or carfilzomib triplet therapy, in the relapsed/refractory setting.

A new guideline for the role of daratumumab in combination with lenalidamide and dexamethasone for patients with relapsed and refractory multiple myeloma has been approved by the Drugs and Therapeutics Committee.

Approved Restriction:
In combination with lenalidamide and dexamethasone for patients with multiple myeloma who have received at least one prior treatment. Patients must be sensitive to lenalidomide or not previously exposed. Treatment should be in patients who have a good performance status. Treatment with daratumumab should continue until disease progression or unacceptable toxicity.

Patients are eligible for only one triplet therapy, i.e. either daratumumab or carfilzomib triplet therapy, in the relapsed/refractory setting.

III. Expanded Guidelines

oBINutuzumab, *Gazyva*®

A new guideline for the role of oBINutuzumab in combination with chemotherapy in patients with follicular lymphoma with disease that is refractory to riTUXimab has been approved by the Drugs and Therapeutics Committee.

Approved Restriction:
In adult patients with follicular lymphoma, or other indolent (low grade) lymphoma, with disease that is refractory to a riTUXimab containing regimen as defined in the GADOLIN trial (no response to, or progression within 6 months of completion of riTUXimab therapy) and with a good performance status.

Patients with disease response to induction treatment with oBINutuzumab plus chemotherapy (6 cycles) or who have stable disease should continue to oBINutuzumab maintenance. Maintenance treatment should continue until disease progression or for up to two years, whichever comes first.

oBINutuzumab maintenance treatment should not be for patients who have progressive disease while on oBINutuzumab induction treatment (i.e., oBINutuzumab plus chemotherapy for 6 cycles).

IV. Medication Policies

The following hospital 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.

CL-UA-001	Heparin Bladder Instillation
MM-MS-015	Redundant Antimicrobial Therapy
CAN-ST-002	Administration of Intravenous Systemic Therapy for Cancer (Cancer Care Directive)

V. Order Sets

The following order sets have been approved by the Medical Advisory Committee on the recommendation of the Drugs and Therapeutics Committee.

PPO 0106 NS	Admission Hemodialysis Orders
PPO 0334 CZ	Oral Contrast Administration for Body CT – Inpatient
PPO 0661 CZ	Cardiology Transfer Orders
PPO 0663 NS	Neurology Orders
PPO 0664 CZ	Parenteral Nutrition Pre-Mix for Interim or Bridging Solution
PPO 0665 NS	Admission Orders – Offender Health Services
PPO 0668 NS	Atezolizumab – Compassionate Use
PPO 0669 NS	Durvalumab-Compassionate Use
PPO 0670 NS	Liposomal Irinotecan/Leucovorin/Fluorouracil – FOLFNALIRI Compassionate Use
CR POPNMO NZ	Post Neuraxial Morphine Orders (for C Section Patients)
CR POIMIGD NZ	Intrapartum Management of Insulin for Gestational Diabetes
PPO 0039 NS	DHAP with/without RiTUXimab (IV/Subcut) Lymphoma
PPO 0084 NS	CHOP/CVP with/without RiTUXimab (IV/Subcut) Lymphoma
PPO 0479 NS	GDP with/without RiTUXimab (IV/Subcut) for relapsed/ Refractory Lymphoma
PPO 0131 NS	PACLItaxel (every 21 days) – Breast Regimen
PPO 0232 NS	Methotrexate – Gyne Gestational Trophoblastic Regimen
PPO 0488 NS	ABVD
PPO 0628 NS	PACLItaxel (Weekly) – Breast Regimen
PPO 0666 NS	Hepatitis B Vacc – Dialysis/Pre-Dialysis – Engerix-B
PPO 0667 NS	Hepatitis B Vacc – Dialysis/Pre-Dialysis – Recombivax HB
PPO 0671 NS	Autologous BEAM Conditioning Transplant Orders Lymphoma
PPO 0672 NS	FOLFIRINOX (modified) – Adjuvant Pancreatic Adenocarcinoma
PPO 0673 NS	VinORELbine Single Agent
PPO 0209 CZ	Continuous Peripheral Nerve Block
PPO 0285 CZ	Continuous Local Anesthetic Infusions (CLAI)– Paravertebral or Transversus Abdominus lane (TAP) Block P
PPO 0383 CZ	Alcohol Withdrawal
NS OSNPWT	Negative Pressure Wound Therapy
PPO 0677 NS	Raltitrexed/Oxaliplatin (TOMOX) – GI Regimen
PPO 0678 NS	VinCRIStine/Cyclophosphamide/Topotecan (VTC) – Relapsed Ewing Sarcoma Regimen
PPO 0679 NS	Temozolomide/VinCRIStine/Irinotecan (VIT) – Relapsed Ewing Sarcoma Regimen
PPO 0634 NZ	Acute Exacerbation of Chronic Obstructive Pulmonary Disease

VI. IV Manual

The Drugs and Therapeutics and Medical Advisory Committees have approved the following IV Manual resources for NSHA:

- NSHA IV Manual (formerly Central Zone IV Manual) for adult patients in NSHA. Currently located on Central Zone website; will be transitioning to NSHA website in August 2019.
- BC Cancer, Cancer Drug Manual for administration of oncology drugs in NSHA. Currently may have to link directly to BC Cancer http://www.bccancer.bc.ca/ Drug monographs will exist within the NSHA IV Manual (Aug 2019) with a link to the BC Cancer drug monograph.
  NOTE: riTUXimab and cyclophosphamide used for non-oncology purposes will have IV monographs in the NSHA IV Manual (Aug 2019).
- IV Manual-Pediatric, IWK for pediatric patients in NSHA. There is a link currently on the Central Zone Intranet homepage under Manuals, IWK Pediatric/Neonatal Drug Dosing Guidelines Choose a drug and a link is provided to parenteral administration guidelines or access the IWK IV Manual using the following link: http://pulse.iwk.nshealth.ca/subsites/page/?id=261

When the NSHA IV Manual site goes live in August it will be located under clinical resources on the NSHA Intranet and will contain links to the three sites specified above. An update memo will accompany the IV Manual launch since numerous drug monographs have been revised to accommodate changes in administration associated with smart pump implementation.

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

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