Nova Scotia Formulary Updates

Changes to Maximum Reimbursable Prices

Provinces and territories are continuing to work together to lower generic drug prices through the pan-Canadian Pharmaceutical Alliance (formerly known as the Pan-Canadian Competitive Value Price Initiative for Generic Drugs).

In 2013, the Council of the Federation announced a price reduction to 18% of the lowest brand price in participating provinces and territories for six generic drug categories, and added four more drugs in April 2014. Effective April 1, 2015, the Maximum Reimbursable Prices (MRPs) of four additional drugs will be reduced to the 18% of Brand level: Clopidogrel, Gabapentin, Metformin, Olanzapine.

Notification of the new prices is being provided at this time to allow pharmacies, manufacturers and wholesalers adequate time to adjust inventories and manage stocks.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>New MRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>clopidogrel 75mg tab</td>
<td>$0.4735</td>
</tr>
<tr>
<td>gabapentin 100mg cap</td>
<td>$0.0749</td>
</tr>
<tr>
<td>gabapentin 300mg cap</td>
<td>$0.1821</td>
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<tr>
<td>gabapentin 800mg tab</td>
<td>$0.4341</td>
</tr>
<tr>
<td>metformin HCl 500mg tab</td>
<td>$0.0444</td>
</tr>
<tr>
<td>metformin HCl 850mg tab</td>
<td>$0.0610</td>
</tr>
<tr>
<td>olanzapine 2.5mg tab</td>
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</tr>
<tr>
<td>olanzapine 5mg tab</td>
<td>$0.6379</td>
</tr>
<tr>
<td>olanzapine 7.5mg tab</td>
<td>$0.9568</td>
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<tr>
<td>olanzapine 10mg tab</td>
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Changes to Maximum Reimbursable Prices Continued…

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>NEW MRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>olanzapine 15mg tab</td>
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<tr>
<td>olanzapine ODT 5mg tab</td>
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<td>olanzapine ODT 15mg tab</td>
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</tr>
<tr>
<td>olanzapine ODT 20mg tab</td>
<td>$2.5447</td>
</tr>
</tbody>
</table>

Auditor’s Corner: Insured Professional Services Summary

Nova Scotia Pharmacare Programs covers several professional services. Below are the highlights of these insured services. For more specific information on billing, please refer to the Pharmacists’ Guide.

Prescription Adaptation

Prescription adaptation is an insured service under all the Pharmacare Programs when it is performed as follows:

Refusal to fill a prescription for a drug monitored by the NSPMP

Note: Refusing to fill a prescription for a monitored drug because it has been requested early is not an insured prescription adaptation service. The PIN for refusal to fill is 93899986.

Claims Submission – Clinical Reason to Enhance Patient Outcomes

Pharmacists may submit claims for prescription adaptation services to the Pharmacare Programs for reimbursement for a clinical reason to enhance patient outcomes provided all of the criteria for coverage are met.

Note: A change in prescription quantity not related to a dose change or duration change is not an insured prescription adaptation service. For example:

- Replacing a 5mg tablet with one-half of a 10mg tablet is not insured.
- Changing quantities for compliance packaging must be authorized by the original prescriber, so it is not a prescription adaptation service and is not insured.
- Changes made to match the quantity prescribed to a commercially available package size are not insured.
- Substituting a strength in the case of a manufacturer shortage (e.g., Synthroid® 0.2mg changed to 2 Synthroid® 0.1mg) is not insured.
- Any change in formulation (e.g., tablet to liquid) is not insured.
- Any change in regimen (e.g., changing therapy from morning to bedtime dosing) is not insured.
Prescription Adaptation Continued...

Prescription adaptation services are eligible for coverage provided all the following conditions are met:

- The original prescription must be a valid complete prescription. This means it includes the:
  - Date of issue
  - Name and address of the patient
  - Name of the drug or ingredients
  - Strength of the drug, where applicable
  - Quantity of the drug that may be dispensed
  - Dosage instructions for the patient
  - Refill authorization, where applicable
  - Name, address, telephone number of prescriber, and a valid and authentic signature in an acceptable print or electronic form

  **NOTE:** The dispenser must verify and complete any incomplete or missing element, but verification and completion of a prescription element is not an insured prescription adaptation service.

- The prescription adaptation service is conducted by a pharmacist licensed with the NSCP.

- The patient is a beneficiary of a Nova Scotia Pharmacare Program.

- The beneficiary gives informed and voluntary consent as described in the NSCP Standards of Practice: Prescribing of Drugs by Pharmacists.

- Pharmacists must comply with all applicable NSCP Standards of Practice: Prescribing of Drugs by Pharmacists.

- Documentation of consent, assessment, monitoring plan, and notification to the prescriber of the medication being substituted is to be kept on file in the pharmacy for at least three (3) years for audit purposes.

The following steps must be completed on the same day in the following order for the pharmacy to be reimbursed for the service:

- The original claim for the prescription as written by the prescriber is submitted to Pharmacare and then reversed.

- A claim for prescription adaptation is submitted using PIN 93899985 for the first adaptation, second adaptation: 93899983, and third adaptation: 93899984

- All CPhA Claims Standard field content included in the CPhA Claims Standard – Prescription Adaptation: Clinical Reason to Enhance Patient Outcomes table is required on the claim.

- The hard copy must reference the prescription numbers for the original claim and the modified claim.

- Pharmacists are permitted to prescribe the prescription adaptation using their NSCP licence number.

- The claim for the new prescription with the changes made is submitted to Pharmacare.

- Claims for prescription adaptation services must be submitted electronically.
Prescription Adaptation Continued...

If more than three prescription adaptation services are required for the same beneficiary on the same day, manual claims shall be submitted to the Pharmacare Programs.

Therapeutic Substitution Service - Proton Pump Inhibitors (PPIs)

Under the authority of the Pharmacist Drug Prescribing Regulations of the Pharmacy Act, pharmacists are able to adapt existing prescriptions to maintain or enhance patient care. Therapeutic substitution within the ATC Code A02BC (Proton Pump Inhibitors-PPIs) is an insured service for beneficiaries of the Nova Scotia Pharmacare Programs.

Therapeutic substitution services for PPIs are eligible for coverage provided all the following conditions are met:

- To allow a beneficiary of a Pharmacare Program access to an open benefit PPI in situations where the beneficiary has been prescribed a non-benefit product and/or one requiring special authorization for payment. Reimbursement is restricted to one payment per beneficiary per year.
- Pharmacists are responsible for determining the appropriateness of the therapeutic substitution before performing the service.
- The therapeutic substitution service is conducted by a pharmacist licensed with the Nova Scotia College of Pharmacists (NSCP).
- The patient is a beneficiary of a Nova Scotia Pharmacare Program.
- Pharmacists must comply with all applicable NSCP Standards of Practice: Prescribing of Drugs by Pharmacist
- The beneficiary provides written consent to authorize the pharmacist to make the therapeutic substitution.

Claims Submission

Pharmacists must submit electronic claims for therapeutic substitution services to the Pharmacare Programs for reimbursement provided all of the criteria for coverage are met. The following steps must be completed on the same day in the following order for the pharmacy to be reimbursed for the service:

- The claim for the prescription as written by the prescriber is submitted to Pharmacare and then reversed/canceled.
- A claim for therapeutic substitution is submitted using PIN 93899912. (This PIN is specific for therapeutic substitutions within the PPI category).
- All CPhA Claims Standard field content included in the CPhA Claims Standard – Therapeutic Substitution is required on the claim.
- The hard copy must reference the prescription numbers for the original claim and modified claim.
- The claim for the new prescription with the changes made is submitted to Pharmacare.
Pharmacists Initiated Prescription

Pharmacists licensed with the Nova Scotia College of Pharmacists may prescribe and submit claims to any of the Nova Scotia Pharmacare Programs for eligible benefits in the following ATC categories in the Nova Scotia Formulary:

- R07AX01 Miscellaneous Respiratory Products (AeroChambers)
- V04CA02 Glucose (Diabetes Supplies listed in the Miscellaneous Section)
- V07AS01 Stomi Equipment (Ostomy Supplies listed in the Miscellaneous Section)

To be eligible for reimbursement:

- The pharmacist must document a prescription for each supply, specifying the number of refills. The prescription must comply with all applicable legislation
- The pharmacist must sign the prescription as the prescriber, thereby assuming full responsibility for the prescription
- Once a product is established for a patient the pharmacist must prescribe a minimum of 30 day supply.
- Prescription must be retained by the pharmacy in compliance with all applicable legislation and must be available for Pharmacare audit.

Claims Submission

Prescriptions for pharmacist-prescribed supplies are to be billed to the Pharmacare Programs for real-time, electronic adjudication as follows:

- Claims must have the pharmacist prescribing number in the Prescriber field.
- Claims must be submitted in accordance with the terms and conditions of the Nova Scotia Pharmacare Tariff Agreement. Reimbursement will be in accordance with the payment rules of the agreement.

Basic Medication Review Service

Basic Medication Review Service (BMRS) – approximately 20 to 30 minutes to complete – is an insured service under all the Pharmacare Programs, except the Under 65 – LTC Program. To qualify for the program:

- The individual must be a beneficiary of a Nova Scotia Pharmacare Program, except the Under 65 – LTC Program.
- The beneficiary must agree with their pharmacist that they are a suitable candidate for the service and sign a consent form which, along with all other documentation, is to be kept on file in the pharmacy for at least three years for audit purposes.
- The beneficiary must not reside in a nursing home, or home for special care.
- The beneficiary must meet with the pharmacist for an in-person consultation.
- The beneficiary must be taking 3 (three) or more prescription medications that are used for the treatment of chronic conditions, and are covered by the Pharmacare Programs.
- The beneficiary must be provided with a comprehensive drug review list that is dated and authorized with the pharmacist’s and the patient’s signatures.
Basic Medication Review Service Continued...

Claims Submission
Pharmacists may submit claims for BMRS to the Nova Scotia Pharmacare Programs for reimbursement provided all the above criteria are met, and the beneficiary has received their comprehensive drug review list dated and authorized with the pharmacist’s and the patient’s signatures, and:

- One BMRS per beneficiary using PIN 93899995 in each benefit year, April 1st to March 31st.
- The service fee for basic medication review (Special Service Code —003) is subject to a PRP of $52.50. The copayment and/or deductible will be applicable to this claim.

Advanced Medication Review Service
Advanced Medication Review Service (AMRS) – approximately one and one-half hours to complete - is an insured service under the Nova Scotia Seniors’ Pharmacare Program. Pharmacies are required to complete the Pharmacy sign-up form and fax it to the Pharmacy Association of Nova Scotia (PANS) prior to offering the service to their patients. It is important for the pharmacy to be registered for billing and audit purposes. To qualify for the program, beneficiaries must:

- Be beneficiaries of the Nova Scotia Seniors’ Pharmacare Program.
- Agree with their pharmacist that they are a suitable candidate for the service. A signed consent form with the pharmacist’s and patient’s signatures and all documentation are to be kept on file in the pharmacy for at least three years for audit purposes.
- Not reside in a nursing home, or home for special care.
- Be taking 4 or more prescription medications; OR taking one of the following:
  - amitriptyline
  - chlordiazepoxide
  - clorazepate
  - cyclobenzaprine
  - diazepam
  - indomethacin
  - methyldopa
- Have at least one of the following diseases:
  - arthritis
  - asthma
  - chronic obstructive pulmonary disease
  - congestive heart failure
  - diabetes
  - hyperlipidemia
  - hypertension
Advanced Medication Review Service Continued...

Claims Submission
Pharmacists may submit claims for AMRS to the Nova Scotia Pharmacare Programs for reimbursement provided the beneficiaries qualify according to the criteria above and:

- One AMRS per beneficiary using PIN 93899999 in each benefit year, April 1st to March 31st.
- The service fee for advanced medication review (Special Service Code “6”) will be subject to a PRP of $150.00. The copayment will be applicable to this claim.
- The special service code “6” is only applicable to the Nova Scotia Seniors’ Pharmacare Program.

Coverage of Continued Care Prescriptions
The Nova Scotia College of Pharmacists (NSCP) have established Conditional Authority Agreements with the College of Physicians and Surgeons of Nova Scotia (CPSNS) as well as the College of Registered Nurses of Nova Scotia (CRNNS), allowing pharmacists to extend existing prescriptions as continued care prescriptions (CCPs), provided certain conditions are met.

Pharmacists may submit claims for CCPs to the Nova Scotia Pharmacare Programs for reimbursement, provided:

- The medication being continued is not a benzodiazepine or a drug monitored by the Nova Scotia Prescription Monitoring Program.
- The CCP is for an eligible benefit under the applicable Pharmacare Program.
- The pharmacist prescribing the CCP is licensed with the NSCP.
- The physician who prescribed the original prescription being extended is licensed with the CPSNS, or the nurse practitioner who prescribed the original prescription being extended is licensed with the CRNNS.
- The patient is a beneficiary of a Nova Scotia Pharmacare Program and has an immediate need for a prescription extension, but their physician or nurse practitioner is unavailable to provide refill authorization.
- The pharmacist is reasonably satisfied that the physician or nurse practitioner, if available, would provide the authorization.
- The medication to be continued is for a chronic or long-term condition.
- The patient has established a stable history with the medication (no recent changes to dosage/drug therapy).
- The prescription is being extended in the same pharmacy where it originated and the patient is under the current care of that pharmacy.
- The prescription has not previously been extended through a CCP.
- The amount of the medication provided does not exceed the previous amount prescribed or one month (30 days), whichever is lesser.
- The CCP is documented in a manner that complies with all applicable legislation. It is assigned its own prescription number and the prescription number of the prescription being extended must be noted on the CCP.
Coverage of Continued Care Prescriptions Continued...

- The pharmacist signs the CCP as the prescriber, thereby assuming full responsibility for the CCP.
- CCPs are retained by the pharmacy in compliance with all applicable legislation and are available for Pharmacare audit (refer to the Audit Section for the prescription audit procedures that apply).
- As with any other prescription, the CCP should be documented on the patient's medication profile.

The primary care physician or nurse practitioner (or physician/nurse practitioner providing overall care to the patient), if different from the prescriber, should be notified of the CCP as soon as reasonably possible. Documentation of such contact is not required for audit purposes.

Claims Submission
CCPs are to be billed to the Pharmacare Programs for real-time electronic adjudication as follows:

All claims must have the NSCP licence number in the Prescriber ID field.

- All claims must include the prescription number assigned to the CCP and have an "N" in the New/Refill code field.
- Claims must be submitted in accordance with the terms and conditions of the Nova Scotia Pharmacare Tariff Agreement. Reimbursement will be in accordance with the payment rules of this agreement.
Nova Scotia Formulary Updates

New Exception Status Benefits

- Harvoni® (ledipasvir/sofosbuvir)
- Sovaldi® (sofosbuvir)
- BREO® ELLIPTA® (fluticasone furoate/vilanterol (as trifenatate))
- Onglyza® (saxagliptin)
- Komboglyze® (saxagliptin and metformin)
- Ibavyr® (ribavirin)

New Product
New Diabetic Products

The following products have been reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as exception status benefits, with the following criteria, effective April 1, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvoni® (ledipasvir/sofosbuvir)</td>
<td>90mg/400mg Tab</td>
<td>02432226</td>
<td>DNP</td>
<td>E</td>
<td>GIL</td>
</tr>
</tbody>
</table>

Criteria

- For treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis) according to the following criteria:
  - Prescribed by a hepatologist or other specialist with expertise in the treatment of hepatitis C
  - Lab-confirmed hepatitis C genotype 1
  - Patient has a quantitative HCV RNA value within the last 6 months
  - Fibrosis stage F2 or greater (Metavir scale or equivalent)

Duration of therapy reimbursed:

<table>
<thead>
<tr>
<th>Genotype 1 Patient Population</th>
<th>Duration of therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment naïve, non-cirrhotic, viral load &lt; 6 M IU/mL</td>
<td>8* weeks</td>
</tr>
<tr>
<td>Treatment naïve, non-cirrhotic, viral load ≥ 6 M IU/mL OR</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Treatment naïve, cirrhotic OR</td>
<td></td>
</tr>
<tr>
<td>Treatment-experienced, non-cirrhotic</td>
<td></td>
</tr>
<tr>
<td>Treatment-experienced, cirrhotic</td>
<td>24 weeks</td>
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</tbody>
</table>
New Exception Status Benefits Continued...

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvoni®</td>
<td>90mg/400mg Tab</td>
<td>02432226</td>
<td>DNP</td>
<td>E</td>
<td>GIL</td>
</tr>
<tr>
<td>(ledipasvir/sofosbuvir)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Criteria

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent
- Patients who have received a previous trial of ledipasvir/sofosbuvir (Re-treatment requests will not be considered)

NOTES:
1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6).
2. Treatment experienced is defined as those who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor.
3. HIV-HCV co-infected patients with Genotype 1 may be considered as per criteria listed above.
4. Treatment of decompensated HCV may be considered for coverage on an exceptional case by case basis.

* For this population cohort, evidence has shown that the SVR rates with the 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized as a Health Canada approved treatment option. Patients may be considered for 12 weeks of coverage if they have borderline or severe fibrosis (F3-4) or if they are co-infected with HIV.

In order to allow for online adjudication the claim must be divided and processed as separate transactions. The following PINs are to be used to bill drug costs in excess of $9,999.99:
- 00904032 and 00904033

Please refer to the Pharmacists’ Guide for billing instructions. The original prescription and refills will be limited to a maximum of 28 days supply at a time.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sovaldi®</td>
<td>400mg Tab</td>
<td>02418355</td>
<td>DNP</td>
<td>E</td>
<td>GIL</td>
</tr>
<tr>
<td>(sofosbuvir)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Criteria
- For the treatment of adult patients with chronic hepatitis C infection with compensated liver disease, (including compensated cirrhosis) as follows:
  - Genotype 1 [for 12 weeks in combination with Pegylated interferon (PegIFN)/Ribavirin (RBV)]:
  - Treatment-naive patients
New Exception Status Benefits Continued...

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sovaldi® (sofosbuvir)</td>
<td>400mg Tab</td>
<td>02418355</td>
<td>DNP</td>
<td>E</td>
<td>GIL</td>
</tr>
</tbody>
</table>

OR **Genotype 2 (for 12 weeks in combination with RBV):**
- Treatment-naive patients in whom interferon (IFN) is medically contraindicated
  OR
- PegIFN/RBV treatment-experienced patients

OR **Genotype 3 (for 24 weeks in combination with RBV):**
- Treatment-naive patients in whom interferon (IFN) is medically contraindicated
  OR
- PegIFN/RBV treatment-experienced patients

AND Who meet ALL of the following:
- Prescribed by a hepatologist or other specialist with expertise in the treatment of hepatitis C.
- Lab-confirmed hepatitis C genotype 1, 2, or, 3
- Patient has a quantitative HCV RNA value within the last 6 months
- Fibrosis stage F2 or greater (Metavir scale or equivalent)

Exclusion criteria:
- Patients currently being treated with another HCV antiviral agent;
- Patients who have previously received a treatment course of sofosbuvir (Re-treatment requests will not be considered).

NOTES:
1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6)
2. Medical contraindication to IFN is defined as hypersensitivity to peginterferon or interferon alfa-2a or 2b, polyethylene glycol or any component of the formulation resulting in discontinuation of therapy; OR presence of significant clinical comorbidities which are deemed to have a high risk of worsening with IFN treatment. Details are required regarding patient’s contraindications and/or risk of worsening significant comorbidities.
3. Treatment-experienced patients (with Genotype 2 or 3) are defined as patients who have previously been treated with PegIFN/RBV and did NOT receive adequate response.
4. HIV-HCV co-infected patients may be considered as per criteria listed above.
5. Treatment of decompensated HCV may be considered for coverage on an exceptional case by case basis.
New Exception Status Benefits Continued...

In order to allow for online adjudication the claim must be divided and processed as separate transactions.

The following PINs are to be used to bill drug cost in excess of $9,999.99:

- 00904041 and 00904042

Please refer to the Pharmacists’ Guide for billing instructions. The original prescription and refills will be limited to a maximum of 28 days supply at a time.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>BREO® ELLIPTA® (fluticasone furoate/vilanterol (as trifenate))</td>
<td>100mcg/25mcg dry powder for inh</td>
<td>02408872</td>
<td>DNP</td>
<td>E</td>
<td>GSK</td>
</tr>
</tbody>
</table>

Criteria

- For the treatment of chronic obstructive pulmonary disease (COPD), if symptoms persist after 2-3 months of short-acting bronchodilator therapy (i.e., salbutamol at a maximum dose of 8 puffs/day or ipratropium at maximum dose of 12 puffs/day).
- Coverage can be provided without a trial of short-acting agent if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction, (postbronchodilator values FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (MRC score of 3-5*)
- Combination therapy with tiotropium and a long-acting beta2 agonist/inhaled corticosteroid will only be considered if:
  - there is spirometric evidence of at least moderate to severe airflow obstruction (postbronchodilator values FEV1 < 60% and FEV1/FVC ratio < 0.7), and significant symptoms (MRC score of 3-5*) and
  - there is evidence of one or more moderate-to-severe exacerbations per year, on average, for 2 consecutive years requiring antibiotics and/or systemic (oral or intravenous) corticosteroids
- If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding severity of condition must be provided for consideration (MRC scale). Spirometry reports from any point in time will be accepted.

*Canadian Thoracic Society COPD Classification By Symptom/Disability:

**Moderate (MRC 3-4):** Shortness of breath from COPD causing the patient to stop after walking about 100 meters (or after a few minutes) on the level.

**Severe (MRC 5):** Shortness of breath from COPD resulting in the patient being too breathless to leave the house or breathless after undressing, or the presence of chronic respiratory failure or clinical signs of right heart failure.

MRC= Medical Research Council Dyspnea Scale
New Exception Status Benefits Continued...

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onglyza® (saxagliptin)</td>
<td>2.5mg Tab</td>
<td>02375842</td>
<td>DNP</td>
<td>E</td>
<td>AZE</td>
</tr>
<tr>
<td></td>
<td>5mg Tab</td>
<td>02333554</td>
<td>DNP</td>
<td>E</td>
<td>AZE</td>
</tr>
</tbody>
</table>

Criteria

- For the treatment of Type II diabetes for patients with:
  - inadequate glycemic control on metformin and a sulfonylurea; and
  - for whom insulin is not an option.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Komboglyze® (saxagliptin and metformin)</td>
<td>2.5mg/500mg Tab</td>
<td>02389169</td>
<td>DNP</td>
<td>E</td>
<td>AZE</td>
</tr>
<tr>
<td></td>
<td>2.5mg/850mg Tab</td>
<td>02389177</td>
<td>DNP</td>
<td>E</td>
<td>AZE</td>
</tr>
<tr>
<td></td>
<td>2.5mg/1000mg Tab</td>
<td>02389185</td>
<td>DNP</td>
<td>E</td>
<td>AZE</td>
</tr>
</tbody>
</table>

Criteria

- For the treatment of Type II diabetes for patients:
  - who are already stabilized on therapy with metformin, a sulfonylurea and saxagliptin to replace the individual components of saxagliptin and metformin; and
  - for whom insulin is not an option.

The following products will be listed as exception status benefits, with the following criteria, effective April 1, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibavyr® (ribavirin)</td>
<td>400mg Tab</td>
<td>02425890</td>
<td>DNP</td>
<td>E</td>
<td>PDP</td>
</tr>
<tr>
<td></td>
<td>600mg Tab</td>
<td>02425904</td>
<td>DNP</td>
<td>E</td>
<td>PDP</td>
</tr>
</tbody>
</table>

Criteria

- For use within a combination therapy regimen for the treatment of chronic hepatitis C, in accordance with the specific eligibility criteria for approved agents.

The original prescription and refills will be limited to a maximum of 28 days supply at a time.
New Product
The following product is a new listing to the Nova Scotia Formulary, effective April 1, 2015. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trelstar® (triptorelin)</td>
<td>22.5mg Inj</td>
<td>02412322</td>
<td>DNP</td>
<td>SFC</td>
<td>ATV</td>
</tr>
</tbody>
</table>

New Diabetic Products
The following products will be new listings to the Nova Scotia Formulary, effective April 1, 2015. The benefit status and reimbursement price within the Nova Scotia Pharmacare Programs is indicated.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>DIN/PIN</th>
<th>MLP</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>MontKiddy Pen Needles, 4mm, 32g, Blue</td>
<td>97799334</td>
<td>0.2799</td>
<td>DNP</td>
<td>SFD</td>
<td>MTD</td>
</tr>
<tr>
<td>MontKiddy Pen Needles, 4mm, 32g, Green</td>
<td>97799337</td>
<td>0.2799</td>
<td>DNP</td>
<td>SFD</td>
<td>MTD</td>
</tr>
<tr>
<td>MontKiddy Pen Needles, 4mm, 32g, Pink</td>
<td>97799335</td>
<td>0.2799</td>
<td>DNP</td>
<td>SFD</td>
<td>MTD</td>
</tr>
<tr>
<td>MontKiddy Pen Needles, 4mm, 32g, Yellow</td>
<td>97799336</td>
<td>0.2799</td>
<td>DNP</td>
<td>SFD</td>
<td>MTD</td>
</tr>
</tbody>
</table>
Nova Scotia Formulary Updates

Minor Ailments Assessment One-Year Demonstration Project

Under the authority of the Pharmacy Act and the Pharmacist Drug Prescribing Regulations, pharmacists are able to prescribe Schedule II and Schedule III drugs to treat a condition, and to prescribe Schedule I drugs in accordance with the standards of practice to treat conditions approved by the Council of the Nova Scotia College of Pharmacists.

As a one-year demonstration project, effective May 4, 2015 to May 3, 2016, pharmacist assessment for three (3) conditions will be an insured service for beneficiaries of the Nova Scotia Pharmacare Programs.

Minor Ailments Assessment services are eligible for coverage provided the following criteria are met:

a) The assessment is for one of the following minor ailments: cold sores; allergic rhinitis; or skin conditions.

b) The assessment is conducted by a pharmacist licensed with the Nova Scotia College of Pharmacists (NSCP).

c) The patient is a beneficiary of a Nova Scotia Pharmacare Program.

d) The pharmacist must comply with all applicable NSCP Standards of Practice: Prescribing of Drugs by Pharmacists.

e) The beneficiary provides written consent for the pharmacist to conduct the assessment.

f) The pharmacist faxes a completed “Minor Ailment Demonstration Project: Pharmacare Form” to 902-428-3400 as soon as possible after submitting a claim for one of the asterisked PINs on the next page. This form is available from the Pharmacy Association of Nova Scotia.
Minor Ailments Assessment One-Year Demonstration Project Continued…

Claims Submission
Pharmacists must submit electronic claims for Minor Ailments Assessment services to the Pharmacare Program for reimbursement.

<table>
<thead>
<tr>
<th>FIELD #</th>
<th>FIELD NAME</th>
<th>CONTENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.56.03</td>
<td>DIN/GP/PIN</td>
<td>XXXXXXXXXX</td>
</tr>
<tr>
<td>D.57.03</td>
<td>Special Service Code</td>
<td>003 (pharmacist consultation)</td>
</tr>
<tr>
<td>D.58.03</td>
<td>Quantity</td>
<td>000001 (one)</td>
</tr>
<tr>
<td>D.61.03</td>
<td>Prescriber ID</td>
<td>NSCP License number</td>
</tr>
<tr>
<td>D.66.03</td>
<td>Drug Cost/Product Value</td>
<td>DDDDD (dollar value – not adjudicated)</td>
</tr>
<tr>
<td>D.67.03</td>
<td>Cost Upcharge</td>
<td>DDDDD (dollar value – not adjudicated)</td>
</tr>
<tr>
<td>D.68.03</td>
<td>Professional Fee</td>
<td>DDDDD (dollar value – not adjudicated)</td>
</tr>
<tr>
<td>D.72.03</td>
<td>Special Service Fee</td>
<td>2000 ($20.00)*</td>
</tr>
</tbody>
</table>

* The copayment and/or deductible will not be applied to this claim.

There are three sets of four PINs, one set of four for each minor ailment.

For Cold Sores:
1. 93899908 - assessment fee when one or more Pharmacare benefits are prescribed, with or without a nonprescription treatment
2. 93899907* - assessment fee when a Schedule I non-Pharmacare benefit is prescribed, with or without a Pharmacare benefit and/or a nonprescription treatment
3. 93899906* - assessment fee when one or more nonprescription treatments are recommended without a Schedule I prescription
4. 93899905* - assessment fee when a referral is made

Beneficiaries are insured for 6 (six) minor ailment assessment fees for cold sores during the demonstration project. Any additional fees will be recovered through post audit.

For Allergic Rhinitis:
1. 93899904 - assessment fee when one or more Pharmacare benefits are prescribed, with or without a nonprescription treatment
2. 93899903* - assessment fee when a Schedule I non-Pharmacare benefit is prescribed, with or without a Pharmacare benefit and/or a nonprescription treatment
3. 93899902* - assessment fee when one or more nonprescription treatments are recommended without a Schedule I prescription
4. 93899901* - assessment fee when a referral is made

Beneficiaries are insured for 4 (four) minor ailment assessment fees for allergic rhinitis during the demonstration project. Any additional fees will be recovered through post audit.
Minor Ailments Assessment One-Year Demonstration Project Continued…

For Skin Conditions:
1. **93899900** - assessment fee when one or more Pharmacare benefits are prescribed, with or without a nonprescription treatment
2. **93899899** - assessment fee when a Schedule I non-Pharmacare benefit is prescribed, with or without a Pharmacare benefit and/or a nonprescription treatment
3. **93899898** - assessment fee when one or more nonprescription treatments are recommended without a Schedule I prescription
4. **93899897** - assessment fee when a referral is made

Beneficiaries are insured for 4 (four) minor ailment assessment fees for skin conditions during the demonstration project. Any additional fees will be recovered through post audit.

* When this PIN is claimed, a completed “Minor Ailment Demonstration Project: Pharmacare Form” must be faxed to 902-428-3400 as soon as possible. Forms are available from the Pharmacy Association of Nova Scotia.

Medication Review Service Follow-Up
Effective **May 4, 2015**, Medication Review Service Follow-Ups will be insured for beneficiaries of the Nova Scotia Pharmacare Programs when eligibility criteria are met.

Please refer to the Pharmacists’ Guide for eligibility criteria, adjudication guidelines, and the PIN.

Provided all of the criteria are met, the Pharmacare Programs shall reimburse a maximum of two (2) Medication Review Follow-Ups per beneficiary within one year of the original Basic or Advanced Medication Review Service.

As with other insured services, this service is subject to audit and documentation must be available.

New Exception Status Benefits
The following products have been reviewed by the Atlantic Common Drug Review (ACDR) and will be listed as exception status benefits, with the following criteria, effective **May 4, 2015**.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>DexIron® (iron dextran)</td>
<td>50mg/mL Inj</td>
<td>02205963</td>
<td>DNP</td>
<td>E</td>
<td>MYL</td>
</tr>
</tbody>
</table>

Criteria
- For the treatment of iron deficiency anemia in patients intolerant to oral iron replacement products OR
- For patients who have not responded to adequate therapy with oral iron.

NOTE:
- Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron.
- Details regarding oral iron tried, length of therapy, and outcome must be provided.
New Exception Status Benefits Continued...

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feraheme® (ferumoxytol)</td>
<td>30mg/mL Inj</td>
<td>02377217</td>
<td>DNP</td>
<td>E</td>
<td>TAK</td>
</tr>
<tr>
<td>Criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For the treatment of iron deficiency anemia in home hemodialysis, peritoneal dialysis and predialysis chronic kidney disease patients. &lt;br&gt;  o Coverage must be requested by a practitioner with a specialty in nephrology. &lt;br&gt;  o Coverage will only be considered if the dose required is ferumoxytol 510mg to avoid wastage and unnecessary costs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>NOTE:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Given the safety concerns with IV iron, patients should be closely monitored for signs and symptoms of hypersensitivity reactions including monitoring of blood pressure and pulse during and for at least 30 minutes following each infusion of Feraheme®. IV iron product monographs recommend IV irons should only be administered when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ferumoxytol is contraindicated in some patients, including those with hypersensitivities to this product, any allergies to other parenteral iron products, and in individuals with any known drug allergy.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ferumoxytol may affect the diagnostic ability of MRI for up to 3 months.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrlecit® (sodium ferric gluconate)</td>
<td>12.5mg/mL Inj</td>
<td>02243333</td>
<td>DNP</td>
<td>E</td>
<td>SAV</td>
</tr>
<tr>
<td>Criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For the treatment of iron deficiency anemia in patients intolerant to oral iron replacement products OR &lt;br&gt;  • For patients who have not responded to adequate therapy with oral iron.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOTE:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron. &lt;br&gt;  • Details regarding oral iron tried, length of therapy, and outcome must be provided.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
New Exception Status Benefits Continued…

The following product was reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as exception status benefits, with the following criteria, effective May 4, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oralair® (grass pollen allergen extract)</td>
<td>300 Unit IR S/L Tab</td>
<td>02381893</td>
<td>DNP</td>
<td>E</td>
<td>STA</td>
</tr>
<tr>
<td></td>
<td>100 Unit IR S/L Tab</td>
<td>02381885</td>
<td>DNP</td>
<td>E</td>
<td>STA</td>
</tr>
</tbody>
</table>

Criteria
- For the seasonal treatment of grass pollen allergic rhinitis in patients that have not adequately responded to, or tolerated, conventional pharmacotherapy.

NOTE:
- Treatment with 5-GPAE must be prescribed and initiated by physicians with adequate training and experience in the treatment of respiratory allergic diseases.
- Treatment should be initiated four (4) months before onset of pollen season and should only be continued until the end of the season.
- Treatment should not be taken for more than three (3) consecutive years.

The following product was reviewed by the pCODR Expert Review Committee (pERC) and will be listed as exception status benefits, with the following criteria, effective May 4, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pomalyst® (pomalidomide)</td>
<td>1mg Cap</td>
<td>02419580</td>
<td>DNP</td>
<td>E</td>
<td>CEL</td>
</tr>
<tr>
<td></td>
<td>2mg Cap</td>
<td>02419599</td>
<td>DNP</td>
<td>E</td>
<td>CEL</td>
</tr>
<tr>
<td></td>
<td>3mg Cap</td>
<td>02419602</td>
<td>DNP</td>
<td>E</td>
<td>CEL</td>
</tr>
<tr>
<td></td>
<td>4mg Cap</td>
<td>02419610</td>
<td>DNP</td>
<td>E</td>
<td>CEL</td>
</tr>
</tbody>
</table>

Criteria
- For patients with relapsed and/or refractory multiple myeloma who have previously failed at least two treatments, including both bortezomib and lenalidomide and demonstrated disease progression on the last treatment.
- Pomalidomide may be an option in rare instances where bortezomib is not tolerated or contraindicated but in all cases, patients should have failed lenalidomide.

NOTE:
- Pomalidomide must be prescribed and dispensed only by physicians and pharmacists who are registered with and agree in writing to adhere to the guidelines of the Company’s RevAid® Program. Details are available at [https://revaid.ca/revaid](https://revaid.ca/revaid).
New Exception Status Benefits Continued...

In order to allow for online adjudication the claim must be divided and processed as separate transactions. The following PINs are to be used to bill drug costs in excess of $9,999.99:

- 1mg: 00904028
- 2mg: 00904029
- 3mg: 00904030
- 4mg: 00904031

Please refer to the Pharmacists’ Guide for billing instructions. The original prescription and refills will be limited to a maximum of 28 days supply at a time.

Criteria Update
The following product was reviewed by the Atlantic Common Drug Review (ACDR) and will be listed with the following new criteria effective May 4, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venofer®</td>
<td>20mg/mL Inj</td>
<td>02243716</td>
<td>DNP</td>
<td>E</td>
<td>MYL</td>
</tr>
<tr>
<td>(iron sucrose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Criteria
- For the treatment of iron deficiency anemia in patients intolerant to oral iron replacement products OR
- For patients who have not responded to adequate therapy with oral iron.

NOTE:
- Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron.
- Details regarding oral iron tried, length of therapy, and outcome must be provided.

Notification of ASA 325mg Delisting
Effective July 1, 2015, the benefit status of ASA 325mg will change from a full benefit to non-insured status. This change will align the coverage of ASA 325mg with ASA 81mg, which is currently a non-benefit. ASA 325mg is an over-the-counter medication which is available at a very low cost for patients who require this therapy.
New Ostomy Products
Effective May 13, 2015, a number of Convatec ostomy products will be added as full benefits under the Nova Scotia Pharmacare Programs. The specific products and associated billing PINs (as per the OPINIONS website) can be found on the most recent update of the Nova Scotia Formulary, which will be available on the Nova Scotia Pharmacare website.

Flat Priced Medications and Prescription Costs
As you may be aware, some medications are the same price for all strengths (i.e. flat priced). Dispensing multiple tablets to equal one higher strength can result in unnecessary costs. For example, if two 5mg tablets of donepezil are dispensed for a 10mg dose then the medication cost is doubled. To protect against these added costs, approvals for some medications (e.g. donepezil 10mg) may be restricted to the strength requested only. Allowances for titration of dose and alternative dosing schedules may be considered on a case-by-case basis.
Nova Scotia Formulary Updates

New Benefits

Based on a review by the Atlantic Common Drug Review (ACDR), effective June 29, 2015, the following products will be listed as full benefits under the Nova Scotia Pharmacare Programs.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dutasteride</td>
<td>0.5mg Cap</td>
<td>Multiple</td>
<td>DNP</td>
<td>SF</td>
<td>VAR</td>
</tr>
<tr>
<td>Finasteride</td>
<td>5mg Tab</td>
<td>Multiple</td>
<td>DNP</td>
<td>SF</td>
<td>VAR</td>
</tr>
</tbody>
</table>

New Exception Status Benefits

The following products have been reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as exception status benefits, with the following criteria, effective June 29, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myrbetriq® (mirabegron)</td>
<td>25mg ER Tab</td>
<td>02402874</td>
<td>DNP</td>
<td>E (SF)</td>
<td>ASL</td>
</tr>
<tr>
<td>Myrbetriq® (mirabegron)</td>
<td>50mg ER Tab</td>
<td>02402882</td>
<td>DNP</td>
<td>E (SF)</td>
<td>ASL</td>
</tr>
</tbody>
</table>

Criteria

- For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency if the patient has had an intolerance or inadequate response to an adequate trial of an anticholinergic therapy.
- Not to be used in combination with other pharmacological treatments of OAB.
New Exception Status Benefits Continued...

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adempas® (riociguat)</td>
<td>0.5mg Tab</td>
<td>02412764</td>
<td>DNP</td>
<td>E (SF)</td>
<td>BAY</td>
</tr>
<tr>
<td></td>
<td>1.0mg Tab</td>
<td>02412772</td>
<td>DNP</td>
<td>E (SF)</td>
<td>BAY</td>
</tr>
<tr>
<td></td>
<td>1.5mg Tab</td>
<td>02412799</td>
<td>DNP</td>
<td>E (SF)</td>
<td>BAY</td>
</tr>
<tr>
<td></td>
<td>2.0mg Tab</td>
<td>02412802</td>
<td>DNP</td>
<td>E (SF)</td>
<td>BAY</td>
</tr>
<tr>
<td></td>
<td>2.5mg Tab</td>
<td>02412810</td>
<td>DNP</td>
<td>E (SF)</td>
<td>BAY</td>
</tr>
</tbody>
</table>

Criteria

- For the treatment of inoperable chronic thromboembolic pulmonary hypertension (CTEPH, World Health Organization [WHO] Group 4) or persistent or recurrent CTEPH after surgical treatment in adult patients (≥18 years of age) with WHO Functional Class (FC) II or III pulmonary hypertension (PH).
- Adempas® should be prescribed by a clinician with experience in the diagnosis and treatment of CTEPH.

The original prescription and refills will be limited to a maximum of 28 days supply at a time.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultibro® Breezhaler® (indacaterol/glycopyrronium)</td>
<td>110mcg/50mcg Cap</td>
<td>02418282</td>
<td>DNP</td>
<td>E (SF)</td>
<td>NVR</td>
</tr>
</tbody>
</table>

Criteria

- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients with an inadequate response to a long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).

Clinical notes:

1. Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV₁ < 60% predicted and FEV₁/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.

   If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e. Medical Research Council (MRC) Dyspnea Scale score of at least Grade 3). MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath (SOB) from COPD or has to stop for breath when walking at own pace on the level.

2. Inadequate response is defined as persistent symptoms after at least 2 months of long-acting beta-agonist (LABA) or long-acting anticholinergic therapy (LAAC).
New Products

The following products are new listings to the Nova Scotia Formulary, effective June 29, 2015. The benefit status within the Nova Scotia Pharmacare Programs is indicated. Where applicable, existing criteria applies.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT-Amlodipine</td>
<td>2.5mg Tab</td>
<td>02297477</td>
<td>DNP</td>
<td>SF</td>
<td>ACT</td>
</tr>
<tr>
<td>Innohep®</td>
<td>8,000IU/0.4mL Inj</td>
<td>02429462</td>
<td>DNP</td>
<td>SFC</td>
<td>LEO</td>
</tr>
<tr>
<td>Innohep®</td>
<td>12,000IU/0.6mL Inj</td>
<td>02429470</td>
<td>DNP</td>
<td>SFC</td>
<td>LEO</td>
</tr>
<tr>
<td>Innohep®</td>
<td>16,000IU/0.8mL Inj</td>
<td>02429489</td>
<td>DNP</td>
<td>SFC</td>
<td>LEO</td>
</tr>
<tr>
<td>Jamp Bisacodyl</td>
<td>5mg Supp</td>
<td>02410893</td>
<td>DNP</td>
<td>C</td>
<td>JPC</td>
</tr>
<tr>
<td>Jamp Bisacodyl</td>
<td>10mg Supp</td>
<td>02361450</td>
<td>DNP</td>
<td>C</td>
<td>JPC</td>
</tr>
<tr>
<td>Jaydess® IUD</td>
<td>13.5mg Insert</td>
<td>02408295</td>
<td>DNP</td>
<td>F</td>
<td>BAY</td>
</tr>
<tr>
<td>Latuda®</td>
<td>20mg Tab</td>
<td>02422050</td>
<td>DNP</td>
<td>E</td>
<td>SEP</td>
</tr>
<tr>
<td>Latuda®</td>
<td>60mg Tab</td>
<td>02413361</td>
<td>DNP</td>
<td>E</td>
<td>SEP</td>
</tr>
</tbody>
</table>

Non Insured Products

The following products will not be insured in the Pharmacare Programs, however, they will be funded through the Exception Drug Fund as per other HIV medications.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tivicay® (dolutegravir)</td>
<td>50mg Tab</td>
<td>02414945</td>
<td>N/A</td>
<td>Not Insured</td>
<td>VIV</td>
</tr>
<tr>
<td>Triumeq® (dolutegravir/abacavir/lamivudine)</td>
<td>50mg/600mg/300mg Tab</td>
<td>02430932</td>
<td>N/A</td>
<td>Not Insured</td>
<td>VIV</td>
</tr>
</tbody>
</table>

Other Funding Decisions

Tykerb (lapatinib) was reviewed by pCODR and it was determined that the criteria will not be expanded to include the use of lapatinib in combination with letrozole for the treatment of postmenopausal patients with hormone receptor positive metastatic breast cancer, whose tumours overexpress the ErB2 (HER2) receptor, and who are suitable for endocrine therapy. The criteria for Tykerb (lapatinib) will remain as it is currently listed.

New Diabetic and Ostomy Products

Effective June 29, 2015, a number of new Hollister CeraPlus ostomy products as well as, FORA Test n’ Go diabetic supplies will be added as full benefits under the Nova Scotia Pharmacare Programs. The specific products and associated billing PINs (as per the OPINIONS website) can be found in the most recent update of the Nova Scotia Formulary, which will be available on the Nova Scotia Pharmacare website.
Nova Scotia Formulary Updates

New Exception Status Benefits

- Holkira™ Pak  
  (ombitasvir/paritaprevir/ritonavir and dasabuvir)
- Moderiba™ (ribavirin)
- Abilify Maintena™  
  (aripiprazole)
- Invokana™ (canagliflozin)
- Anoro™ Ellipta®  
  (umeclidinium (as bromide) and ilanterol (as trifenatate))
- Inspra® (eplerenone)
- Vyvanse®  
  (lisdexamefetamine dimesylate)

Non Insured Products

- Nesina™ (alogliptin benzoate)
- Kazano™ (alogliptin benzoate and metformin hydrochloride)

Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2015-16 Influenza Season

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Nova Scotia Formulary Updates

New Exception Status Benefits

The following products have been reviewed by the Canadian Drug Expert Committee (CDEC) and will be listed as exception status benefits, with the following criteria, effective September 1, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
</table>
| Holkira™ Pak  
  (ombitasvir/paritaprevir/ritonavir and dasabuvir) | 12.5/75/50mg and 250mg Tab | 02436027 | DNP | E (SF) | ABV |

Criteria

- For treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis) according to the following criteria:
  - Prescribed by a hepatologist or other specialist with expertise in the treatment of hepatitis C;
  - Lab-confirmed hepatitis C genotype 1, sub-type 1a and 1b required;
  - Patient has a quantitative HCV RNA value within the last 6 months;
  - Fibrosis stage F2 or greater (Metavir scale or equivalent);

Duration of therapy reimbursed:

**Genotype 1 Patient Population**

- Treatment naïve and experienced Genotype 1b, non-cirrhotic**
  - 12 Weeks
- Treatment naïve and experienced Genotype 1a, non-cirrhotic
  - 12 Weeks in combination with ribavirin (Moderiba)
New Exception Status Benefits Continued...

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holkira™ Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir)</td>
<td>12.5/75/50mg and 250mg Tab</td>
<td>02436027</td>
<td>DNP</td>
<td>E (SF)</td>
<td>ABV</td>
</tr>
</tbody>
</table>

Criteria

Genotype 1 Patient Population

Treatment naïve and experienced Genotype 1b, cirrhotic

Treatment naïve and experienced (prior relapsers and prior partial responders) Genotype 1a, cirrhotic

Treatment experienced genotype 1a, with cirrhosis AND who have had a previous null response to PegIFN and RBV

Duration of Therapy

12 Weeks in combination with ribavirin (Moderiba)

12 Weeks in combination with ribavirin (Moderiba)

24 Weeks in combination with ribavirin (Moderiba)

**Holkira Pak with ribavirin is recommended in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.**

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent
- Patients who have received a previous trial of Holkira Pak (Re-treatment requests will NOT be considered)
- Decompensated patients
- No funding for other genotypes except as noted in the above funding criteria for genotype 1
- Patients who have received previous NS3/4A protease inhibitor-based regimens (boceprevir, telaprevir, and simeprevir-based regimens)
- Patients who have received previous sofosbuvir-based regimens (including ledispavir/sofosbuvir)

Notes:

1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6)
2. Treatment experienced patients are defined as those who have previously been treated with PegIFN/RBV and did NOT receive adequate response.
3. HIV-HCV co-infected patients with genotype 1 may be considered as per criteria listed above

The original prescription and refills will be limited to a maximum of 28 days supply at a time.

See billing information on next page.
New Exception Status Benefits Continued...

In order to allow for online adjudication the claim must be divided and processed as separate transactions. The following PINs are to be used to bill drug costs in excess of $9,999.99:

- 00904081 and 00904082

Please refer to the *Pharmacists’ Guide* for billing instructions.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderiba™ (ribavirin)</td>
<td>200mg Tab</td>
<td>02436396</td>
<td>DNP</td>
<td>E (SF)</td>
<td>ABV</td>
</tr>
<tr>
<td></td>
<td>400mg Tab</td>
<td>02426418</td>
<td>DNP</td>
<td>E (SF)</td>
<td>ABV</td>
</tr>
<tr>
<td></td>
<td>600mg Tab</td>
<td>02436426</td>
<td>DNP</td>
<td>E (SF)</td>
<td>ABV</td>
</tr>
</tbody>
</table>

**Criteria**
- For use in chronic hepatitis C patients, genotype 1, who have been approved for coverage of Holkira Pak

**Decision Highlights**
- The manufacturer will provide ribavirin (Moderiba) free of charge to all patients, regardless of whether they choose to participate in the patient assistance program or not. Any inquiries should be directed to AbbVie Care at 1-844-471-CARE (2273).

**Billing Information**
- Dispensing pharmacies can submit a claim with a drug cost and upcharge of $0.00 and the usual and customary dispensing fee.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abilify Maintena™ (aripiprazole)</td>
<td>300mg prolonged release injectable suspension</td>
<td>02420864</td>
<td>DNP</td>
<td>E (SF)</td>
<td>OTS</td>
</tr>
<tr>
<td></td>
<td>400mg prolonged release injectable suspension</td>
<td>02420872</td>
<td>DNP</td>
<td>E (SF)</td>
<td>OTS</td>
</tr>
</tbody>
</table>

**Criteria**
- For the maintenance treatment of schizophrenia in adult patients who are stabilized on oral aripiprazole, and who have:
  - problems with compliance with oral treatments or
  - inadequate control or significant side-effects (e.g. EPS or TD) from one or more conventional depot antipsychotic agents
New Exception Status Benefits Continued...

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invokana™ (canagliflozin)</td>
<td>100mg Tab</td>
<td>02425483</td>
<td>DNP</td>
<td>E (SF)</td>
<td>JAN</td>
</tr>
<tr>
<td></td>
<td>300mg Tab</td>
<td>02425491</td>
<td>DNP</td>
<td>E (SF)</td>
<td>JAN</td>
</tr>
</tbody>
</table>

Criteria
- For the treatment of Type II diabetes for patients with:
  - inadequate glycemic control on metformin and a sulfonylurea; and
  - for whom insulin is not an option

Note:
- 200mg is not a recognized dose; as such a dose of two 100mg tablets will not be funded.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anoro™ Ellipta® (umeclidinium (as bromide) and vilanterol (as trifenate))</td>
<td>62.5mcg/25mcg dry powder for oral inh</td>
<td>02418401</td>
<td>DNP</td>
<td>E (SF)</td>
<td>GSK</td>
</tr>
</tbody>
</table>

Criteria
- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients with an inadequate response to a long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).

Notes:
- Moderate to severe COPD is defined by spirometry (post-bronchodilator) FEV1 < 60% predicted and FEV1/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.

  If spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e. Medical Research Council (MRC) Dyspnea Scale score of at least Grade 3). MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath (SOB) from COPD or has to stop for breath when walking at own pace on the level.

- Inadequate response is defined as persistent symptoms after at least 2 months of long-acting beta agonist (LABA) or long-acting anticholinergic therapy (LAAC).
**New Exception Status Benefits Continued…**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inspra®</strong></td>
<td>25mg Tab</td>
<td>02323052</td>
<td>DNP</td>
<td>E (SF)</td>
<td>PFI</td>
</tr>
<tr>
<td><strong>(eplerenone)</strong></td>
<td>50mg Tab</td>
<td>02323060</td>
<td>DNP</td>
<td>E (SF)</td>
<td>PFI</td>
</tr>
</tbody>
</table>

Criteria

- For patients >55 years with mild to moderate HF on standard HF treatments with EF≤ 30% (or ≤35% if QRS duration >130ms) and recent (6 months) hospitalization for CV disease or with elevated BNP or NT-proBNP levels.

Notes:

- Requests will be considered from practitioners with a specialty in cardiology.
- Patients must be on optimal therapy with an angiotensin-converting–enzyme (ACE) inhibitor, an angiotensin-receptor blocker (ARB), or both and a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose.

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The following product will be added as an exception status benefit effective **September 1, 2015.**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vyvanse®</strong></td>
<td>10mg Cap</td>
<td>02439603</td>
<td>DNP</td>
<td>E (F)</td>
<td>SHI</td>
</tr>
<tr>
<td><strong>(lisdexamfetamine dimesylate)</strong></td>
<td>20mg Cap</td>
<td>02347156</td>
<td>DNP</td>
<td>E (F)</td>
<td>SHI</td>
</tr>
<tr>
<td></td>
<td>30mg Cap</td>
<td>02322951</td>
<td>DNP</td>
<td>E (F)</td>
<td>SHI</td>
</tr>
<tr>
<td></td>
<td>40mg Cap</td>
<td>02347164</td>
<td>DNP</td>
<td>E (F)</td>
<td>SHI</td>
</tr>
<tr>
<td></td>
<td>50mg Cap</td>
<td>02322978</td>
<td>DNP</td>
<td>E (F)</td>
<td>SHI</td>
</tr>
<tr>
<td></td>
<td>60mg Cap</td>
<td>02347172</td>
<td>DNP</td>
<td>E (F)</td>
<td>SHI</td>
</tr>
</tbody>
</table>

Criteria

- For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients age 6 to 25 years who:
  - Demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning; and
  - Have been tried on methylphenidate (immediate release or long-acting formulation) or dexamphetamine with unsatisfactory results.

Notes:

- Requests will be considered from specialists in pediatric psychiatry, pediatricians or general practitioners with expertise in ADHD.
- The maximum dose reimbursed is 60mg daily.
Non Insured Products
The following products were reviewed by the Canadian Drug Expert Committee (CDEC) and were not recommended to be listed as benefits under the Nova Scotia Pharmacare Program.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nesina™</strong> (alogliptin benzoate)</td>
<td>6.25mg Tab</td>
<td>02417189</td>
<td>N/A</td>
<td>Not Insured</td>
<td>TAK</td>
</tr>
<tr>
<td></td>
<td>12.5mg Tab</td>
<td>02417197</td>
<td>N/A</td>
<td>Not Insured</td>
<td>TAK</td>
</tr>
<tr>
<td></td>
<td>25mg Tab</td>
<td>02417200</td>
<td>N/A</td>
<td>Not Insured</td>
<td>TAK</td>
</tr>
<tr>
<td><strong>Kazano™</strong> (alogliptin benzoate and metformin)</td>
<td>12.5mg/500mg Tab</td>
<td>02417219</td>
<td>N/A</td>
<td>Not Insured</td>
<td>TAK</td>
</tr>
<tr>
<td></td>
<td>12.5mg/850mg Tab</td>
<td>02417227</td>
<td>N/A</td>
<td>Not Insured</td>
<td>TAK</td>
</tr>
<tr>
<td></td>
<td>12.5mg/1000mg Tab</td>
<td>02417235</td>
<td>N/A</td>
<td>Not Insured</td>
<td>TAK</td>
</tr>
</tbody>
</table>

Decision Highlights
- The single randomized controlled study reviewed had several significant limitations. Therefore, the comparative clinical benefit of these products relative to other less costly oral agents is uncertain.
Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2015-16 Influenza Season

Who is eligible to have publicly-funded influenza vaccine administered by a pharmacist?
All individuals 5 years of age and over can have publicly-funded influenza vaccine administered by a pharmacist. As publicly-funded influenza vaccine is available free of charge, no individual is to be charged for the vaccine.

Who is eligible to have the influenza vaccine administration fee publicly-funded?
Only residents with a valid Nova Scotia Health Card Number are eligible to have the influenza vaccine administration fee billed to Pharmacare. There are no copayments or deductibles associated with the administration of the influenza vaccine to residents with a valid Nova Scotia Health Card Number. All other individuals are responsible for paying the applicable administration fee.

Which pharmacies are eligible to bill for the administration of publicly-funded influenza vaccine?
Pharmacies set up as providers to bill publicly-funded influenza vaccine administration fees last year are already set up for the 2015-16 influenza season. However, all pharmacies are still required to contact their local Nova Scotia Health Authority public health office to confirm their email, dispensary telephone number, and their preferred method for being contacted by public health.

Pharmacies that have not yet been set up as a provider to bill publicly-funded influenza vaccine administration must:

1. Comply with the required training and application expectations set out by the Pharmacist Extended Practice Regulations and the NSCP’s Standards of Practice: Drug Administration.
2. Sign the Confirmation of Agreement Form for Pharmacist Administered Publicly Funded Seasonal Influenza Vaccine (available in the Pharmacists’ Guide) and submit it to Medavie Blue Cross. Medavie Blue Cross will confirm by email or facsimile that the pharmacy has been set up as a provider to bill influenza vaccine administration fees.
3. Provide their local public health office with their provider confirmation and any other information the public health office requires to issue influenza vaccine to the pharmacy.

Where do pharmacies get publicly-funded influenza vaccine?
All publicly-funded influenza vaccine must be obtained from the local public health office. All providers are responsible for any transportation costs to obtain publicly-funded vaccine. Pharmacies should contact their local public health office to place their order for vaccine and to arrange pick-up. Review the packing protocol for transporting biologicals in the Nova Scotia Immunization Manual (located at: http://novascotia.ca/dhw/cdpc/documents/Immunization-Manual.pdf) to ensure you have all the required equipment when you pick up your vaccine. Public health can only release vaccine in accordance with this protocol.

When can pharmacists begin administering publicly-funded influenza vaccine?
No publicly-funded influenza vaccine is to be administered prior to the launch date announced by Public Health in the Nova Scotia Department of Health and Wellness. Claims for the administration fee submitted before the announced start date will subsequently be reclaimed by Pharmacare.
Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2015-16 Influenza Season Continued…

How do pharmacies bill Pharmacare for influenza vaccine administration fees?

Fees for the administration of publicly-funded influenza vaccine to Nova Scotia residents with a valid Nova Scotia Health Card must be billed to Pharmacare online. The electronic claim must contain the following in the patient’s insurance field:

Patient ID – the patient’s Nova Scotia Health Card Number

Carrier ID – NS

If a patient is already set up in the pharmacy system with Pharmacare coverage (e.g., Seniors’ Pharmacare, Family Pharmacare), a separate patient file does not need to be created.

Claims must be submitted using the DIN of the vaccine administered to the patient, unless the patient is pregnant or is a child receiving a second vaccine dose. The following Table provides direction related to submitting claims using a PIN for pregnant women or children receiving a second dose.

Claims Submission Field Content for Pharmacist-Administered Publicly Funded Influenza Vaccines

<table>
<thead>
<tr>
<th>CPhA Claim Standard Field #</th>
<th>CPhA Claim Standard Field Name</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>D.56.03</td>
<td>DIN/GP#/PIN</td>
<td>DINs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fluzone® Quadrivalent 02420643</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FluLaval™ Tetra 02420783</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PIN for pregnant women</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fluzone® Quadrivalent 93899895</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FluLaval™ Tetra 93899893</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PIN for second dose for children</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fluzone® Quadrivalent 93899896</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FluLaval™ Tetra 93899894</td>
</tr>
<tr>
<td>D.58.03</td>
<td>Quantity</td>
<td>000001 (one)</td>
</tr>
<tr>
<td>D.61.03</td>
<td>Prescriber ID</td>
<td>Pharmacists prescriber ID</td>
</tr>
<tr>
<td>D.66.03</td>
<td>Drug Cost/Product Value</td>
<td>DDDDD (dollar value - not adjudicated)</td>
</tr>
<tr>
<td>D 67.03</td>
<td>Cost Upcharge</td>
<td>DDDDD (dollar value - not adjudicated)</td>
</tr>
<tr>
<td>D.68.03</td>
<td>Professional Fee</td>
<td>$12.00 (April 1, 2015 - March 31, 2016)</td>
</tr>
</tbody>
</table>

Claims are submitted with the administration fee in the professional fee field. Providers are not reimbursed for ingredient costs or markups for these claims as they are able to access publicly-funded vaccine at no charge.

What documentation does a pharmacy need to retain for audit and other purposes?

Pharmacies must retain the signed patient Consent and Disclosure form for each claim reimbursed by Pharmacare.

Pharmacies are advised to maintain a record of the quantity of influenza vaccine administered to individuals who do not have a valid Nova Scotia Health Card Number, as this information may be requested by public health.
How do I report an adverse event following immunization (AEFI)?

It is possible that reactions may occur after administration of influenza vaccine, without a causal association to the vaccine. These reactions must be reported to your local Nova Scotia Health Authority public health office for the appropriate follow-up. Providers should document an AEFI using the Public Health Agency of Canada AEFI form (located at: http://www.phac-aspc.gc.ca/im/pdf/raefi-dmcisi-eng.pdf) and forward the form to the local public health office. The local public health office reviews these reports and enters them in their local database before forwarding them to the Public Health Agency of Canada.

What do I do if there is a break in the cold chain?

Cold chain refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting with the manufacturer and ending with the administration of the vaccine. When vaccines are exposed to temperatures of less than 2°C or more than 8°C, the result is a break in the cold chain. Vaccines affected by a break in the cold chain must be packaged separately, identified with a sticker reading “DO NOT USE,” and stored in a refrigerator at between 2°C and 8°C separately from vaccines in current use. Contact your local public health office to determine whether or not they can be used.
Nova Scotia Formulary Updates

Update on the Publicly-Funded Influenza Vaccine

When Pharmacists May Begin Administering

In the last Pharmacare News Bulletin (Volume 15-05) the information regarding pharmacist-administered publicly-funded influenza vaccine indicated no vaccine is to be administered prior to the launch date announced by Public Health. This has been amended and pharmacists may begin administering publicly-funded influenza vaccine as soon as they receive it.

The complete list of DINs and PINs is as follows:

**DINs** | **PIN for pregnant women**
--- | ---
FluLaval Tetra® | 02420783 FluLaval Tetra® 93899893
Fluzone Quadrivalent® MDV | 02432730 Fluzone Quadrivalent® 93899895
Fluzone Quadrivalent® PFS | 02420643

**PIN for second dose for children**

FluLaval Tetra® | 93899894
Fluzone Quadrivalent® | 93899896

Changes to Pharmacare’s Adjudication System

Effective November 2, 2015, there will be an adjustment to the Pharmacare adjudication system that will ensure that any approved exception status drug (ESD) is billed to the correct program. Patients with the Palliative Home Care Drug Coverage Program and/or the Drug Assistance for Cancer Patients Program and an approved ESD may notice a change and may now have a copay as the ESD adjudicates to the correct program. Claims are to continue to be submitted online according to current claim submission guidelines. If you or your patients have any questions please call the Nova Scotia Pharmacare Programs at 902-429-6565 or Toll-free: 1-800-544-6191.

As a reminder, as with all Pharmacare programs, if the patient has any other source of coverage (e.g. private insurance, etc.), that plan must be billed first.
New Exception Status Benefits

The following product has been reviewed by the Common Drug Review (CDR) and will be listed as an exception status benefit, with the following criteria, effective November 2, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tysabri®</td>
<td>300mg/15mL Vial</td>
<td>02286386</td>
<td>DNP</td>
<td>E (SF)</td>
<td>BIG</td>
</tr>
<tr>
<td>(natalizumab)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Criteria

Initial Request:

For the treatment of Relapsing-Remitting Multiple Sclerosis (RRMS) who meet all the following criteria:

- The patient’s physician is a neurologist experienced in the management of relapsing-remitting multiple sclerosis (RRMS); AND
- The patient;
  - Has a current EDSS less than or equal to 5.0; AND
  - Has failed to respond to a full and adequate course* (at least six months) of at least ONE disease modifying therapy OR has contraindications/intolerance to at least TWO disease modifying therapies; AND
  - Has had ONE of the following types of relapses in the past year:
    - The occurrence of one relapse with partial recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI; OR
    - The occurrence of two or more relapses with partial recovery during the past year; OR
    - The occurrence of two or more relapses with complete recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI.
- Approval period: 1 year

Requirements for Initial Requests:

- The patient’s physician provides documentation setting out the details of the patient’s most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, the dates, and the neurological findings.
- MRI reports do NOT need to be submitted with the initial request

* Failure to respond to a full and adequate course is defined as a trial of at least one approved first line therapy for a minimum of 6 months AND experienced at least one disabling relapse (attack) while on this therapy.
New Exception Status Benefits Continued...

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PREScriber</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tysabri®</td>
<td>300mg/15mL Vial</td>
<td>02286386</td>
<td>DNP</td>
<td>E (SF)</td>
<td>BIG</td>
</tr>
</tbody>
</table>

Criteria

Renewal:
- Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within the last 90 days) AND
- Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year; AND
- Recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.0.

The original prescription and refills will be limited to a maximum of 28 days supply at a time.

The following product has been reviewed by the pCODR Expert Review Committee (pERC) and will be listed as an exception status benefit, with the following criteria, effective November 2, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PREScriber</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imbruvica®</td>
<td>140mg Cap</td>
<td>02434407</td>
<td>DNP</td>
<td>E (SFC)</td>
<td>JAN</td>
</tr>
</tbody>
</table>

Criteria

As a treatment option for patients with relapsed and/or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) who have received at least one prior therapy and are considered inappropriate for treatment or retreatment with a fludarabine-based regimen, including:
- Patients who received prior fludarabine-based treatment and had a progression free interval of less than three years
- Patients who received prior fludarabine-based treatment and had a progression free interval of greater than three years, but are now considered unfit for fludarabine-based retreatment due to age ≥ 70, or age ≥ 65 and the presence of comorbidities (Cumulative Illness Rating Scale [CIRS] ≥ 6 or creatinine clearance <70ml/min)
- Patients who did not receive prior fludarabine-based treatment because they were considered unfit, and who relapsed after at least two cycles of alkylator-based therapy, regardless of the progression free interval after that therapy

The original prescription and refills will be limited to a maximum of 28 days supply at a time.
Criteria Updates

The criteria for coverage for buprenorphine/naloxone in the Nova Scotia Pharmacare Programs has been updated to include physicians who have been registered to prescribe buprenorphine/naloxone with the College of Physicians and Surgeons in Nova Scotia (CPSNS) as indicated below:

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine/Naloxone</td>
<td>2mg/0.5mg SL Tab</td>
<td>Various</td>
<td>DN</td>
<td>E (SF)</td>
<td>VAR</td>
</tr>
<tr>
<td>(Brand and generics)</td>
<td>8mg/2mg SL Tab</td>
<td>Various</td>
<td>DN</td>
<td>E (SF)</td>
<td>VAR</td>
</tr>
</tbody>
</table>

Criteria

- For the treatment of opioid dependence for patients in whom methadone is contraindicated (e.g., patients at high risk of, or with, QT prolongation, or hypersensitivity to methadone)
- For the treatment of opioid dependence for appropriate patients ages 18-24 years
- Must be prescribed by a physician licensed to prescribe methadone for opioid dependence or by a physician registered to prescribe buprenorphine/naloxone for opioid dependence with the College of Physicians and Surgeons of Nova Scotia (CPSNS).

NOTE:

- CPSNS requires physicians wishing to expand their scope of practice to include the use of buprenorphine/naloxone in the treatment for opioid dependence to complete the online CAMH Buprenorphine-Assisted Treatment of Opioid Dependence course. Information regarding the course can be found at the following link: [http://www.camh.ca/en/education/about/AZCourses/Pages/BUP.aspx](http://www.camh.ca/en/education/about/AZCourses/Pages/BUP.aspx)

The following product was reviewed by the Atlantic Common Drug Review (ACDR) and will be listed with the following new criteria effective November 2, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valganciclovir</td>
<td>450mg Tab</td>
<td>Various</td>
<td>DNP</td>
<td>E (SFC)</td>
<td>VAR</td>
</tr>
</tbody>
</table>

Criteria

- For the treatment of cytomegalovirus (CMV) retinitis in HIV-positive patients, upon the request of an infectious disease specialist or prescriber with a specialty in infectious disease
- For the prevention of CMV disease post solid organ transplantation in patients at high-risk (D+ / R-) (i.e., donor positive/recipient negative). Coverage will be for a maximum of 90 days
- For the treatment of patients with CMV infection who have received a solid organ transplant.
Criteria Updates Continued…

The following products were reviewed by the pCODR Expert Review Committee (pERC) and will be listed with the following new criteria effective November 2, 2015.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
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<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xtandi® (enzalutamide)</td>
<td>40mg Tab</td>
<td>02407329</td>
<td>DNP</td>
<td>E (SFC)</td>
<td>ASL</td>
</tr>
<tr>
<td>Criteria</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Asymptomatic or mildly symptomatic Patients</td>
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</tr>
<tr>
<td>• As a single agent treatment for asymptomatic or mildly symptomatic metastatic CRPC patients after failure of androgen deprivation therapy (including an LHRH agonist/antagonist or orchiectomy) who have not received prior chemotherapy for metastatic CRPC, ECOG PS 0-1 and no risk for seizures.</td>
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<tr>
<td>• Enzalutamide would be an alternative to abiraterone and not sequential therapy in this asymptomatic or mildly symptomatic patient population.</td>
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<tr>
<td>Symptomatic (post-docetaxel chemotherapy) Patients:</td>
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<tr>
<td>• As a single agent treatment for metastatic CRPC patients with ECOG PS 0-2, no risk for seizures and progression after previous treatment with docetaxel.</td>
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<tr>
<td>• Enzalutamide would be an alternative to abiraterone and not sequential therapy in this symptomatic post docetaxel chemotherapy setting.</td>
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<tr>
<td>Retreatment:</td>
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<tr>
<td>• Use of enzalutamide in the post docetaxel setting is not permitted if previously used in the pre-chemotherapy setting.</td>
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<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Zytiga® (abiraterone acetate)</td>
<td>250mg Tab</td>
<td>02371065</td>
<td>DNP</td>
<td>E (SFC)</td>
<td>JAN</td>
</tr>
<tr>
<td>Criteria</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Asymptomatic or mildly symptomatic Patients:</td>
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<td></td>
</tr>
<tr>
<td>• In combination with prednisone for asymptomatic or mildly symptomatic metastatic CRPC patients after failure of androgen deprivation therapy (including an LHRH agonist/antagonist or orchiectomy) who have not received prior chemotherapy for metastatic CRPC and have ECOG PS 0 or 1.</td>
<td></td>
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<tr>
<td>• Abiraterone would be an alternative to enzalutamide and not sequential therapy in this asymptomatic or mildly symptomatic patient population.</td>
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</tr>
<tr>
<td>Symptomatic (post-docetaxel chemotherapy) Patients:</td>
<td></td>
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<td></td>
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<tr>
<td>• In combination with prednisone for metastatic CRPC patients with ECOG PS of 0-2 and progression after previous treatment with docetaxel.</td>
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<tr>
<td>• Abiraterone would be an alternative to enzalutamide and not sequential therapy in this symptomatic post docetaxel chemotherapy setting.</td>
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</tbody>
</table>
Criteria Updates Continued...

<table>
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<tr>
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<tbody>
<tr>
<td>Zytiga® (abiraterone acetate)</td>
<td>250mg Tab</td>
<td>02371065</td>
<td>DNP</td>
<td>E (SFC)</td>
<td>JAN</td>
</tr>
</tbody>
</table>

Criteria

Retreatment:
- Use of abiraterone in the post-docetaxel setting is not permitted if previously used in the pre-chemotherapy setting.

Criteria Update: Exception Status Criteria for Certain Chronic Obstructive Pulmonary Disease (COPD) Medications

Effective **November 2, 2015**, the criteria for all listed long-acting beta-2 agonists (LABA), long-acting anticholinergics (LAAC), and long-acting beta-2 agonists/Inhaled corticosteroid (LABA/ICS) will be updated to the following:

- For the treatment of moderate to severe chronic obstructive pulmonary disease (COPD) as defined by spirometry.
  
  OR

- For the treatment of COPD in patients with an inadequate response to short acting bronchodilators.

- Combination therapy with a long-acting beta-2 agonist/inhaled corticosteroid (LABA/ICS) and a long-acting anticholinergic (LAAC) inhaler will be considered in patients with: moderate to severe COPD, as defined by spirometry, a history of COPD exacerbation(s) and an inadequate response to LABA/ICS or LAAC.

NOTE:

- Coverage for LABA and LAAC as two separate inhalers will not be considered.

Clinical Notes:

1. Moderate to severe COPD is defined by spirometry as a post bronchodilator FEV1 < 60% predicted and FEV1/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.
   
   If spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided, i.e., Medical Research Council (MRC) Dyspnea Scale Score of at least Grade 3.
   
   MRC Grade 3 is described as: walks slower than people of same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level.

2. Inadequate response to short acting bronchodilators is defined as persistent symptoms, i.e., MRC of at least Grade 3, after at least 2 months of short acting bronchodilator at the following doses*:
   - 8 puffs per day of short acting beta-2 agonist or
   - 12 puffs per day of ipratropium or
   - 6 puffs per day of ipratropium plus salbutamol combination inhaler

   * Inadequate response to LABA/ICS or LAAC is defined as persistent symptoms after at least 2 months of therapy.

3. COPD exacerbation is defined as an increase in symptoms requiring treatment with antibiotics and/or systemic (oral or intravenous) corticosteroids.
Criteria Update: Exception Status Criteria for Certain Chronic Obstructive Pulmonary Disease (COPD) Medications

Continued...

**Treatment of COPD**

Please note that inhaled corticosteroids in combination with long-acting beta₂-agonists (LABA/ICS) have been associated with an increased risk of pneumonia in patients with COPD. Guidelines recommend their use in moderate to severe COPD patients who are experiencing frequent exacerbations, not controlled by long-acting bronchodilators. For patients with moderate to severe COPD who are not experiencing frequent exacerbations, long-acting beta₂ agonists or long-acting anticholinergics are recommended.

Global strategy for the diagnosis, management and prevention of COPD 2015


**NOTE:** Inhalers which combine a LABA/LAAC are also available as ESD benefits. These products have their own criteria which are listed in the NS Formulary.

**Update to Days Supply Limits for Kalydeco® Prescriptions**

Effective **November 2, 2015**, if a beneficiary has coverage for Kalydeco®, the original prescription and refills will be limited to a maximum of 28 days supply at a time.

**New Products**

The following products are new listings to the Nova Scotia Formulary, effective **November 2, 2015**. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>STRENGTH</th>
<th>DIN</th>
<th>PRESCRIBER</th>
<th>BENEFIT STATUS</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combivent Respimat</td>
<td>100/20mcg Sol</td>
<td>02419106</td>
<td>DNP</td>
<td>SFC</td>
<td>BOE</td>
</tr>
<tr>
<td>Nuvaring</td>
<td>11.4mg/2.6mg</td>
<td>02253186</td>
<td>DNP</td>
<td>F</td>
<td>FRS</td>
</tr>
<tr>
<td>ODAN-Sodium Chloride</td>
<td>5% Oph Oint</td>
<td>80046696</td>
<td>DNP</td>
<td>SF</td>
<td>ODN</td>
</tr>
<tr>
<td>ODAN-Sodium Chloride</td>
<td>5% Oph Sol</td>
<td>80046737</td>
<td>DNP</td>
<td>SF</td>
<td>ODN</td>
</tr>
</tbody>
</table>

**New Ostomy Products**

Effective **November 2, 2015**, a number of new Hollister ostomy products will be added as full benefits under the Nova Scotia Pharmacare Programs. The specific products and associated billing PINs (as per the OPINIONS website) can be found in the most recent update of the Nova Scotia Formulary, which will be available on the Nova Scotia Pharmacare website.