

# PharmacareNEWS

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### New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Skyrizi (risankizumab)	75mg/ 0.83mL Pre-filled Inj	02487454	DNP	E (SF)	ABV

#### Criteria

- For patients with severe, debilitating chronic plaque psoriasis (PsO) who meet all of the following criteria:
  - Body Surface Area (BSA) involvement of >10% and/or significant involvement of the face, hands, feet or genitals
  - Failure to respond to, contraindication to or intolerant of methotrexate and cyclosporine
  - Failure to respond to, intolerant of or unable to access phototherapy
  - Written request of a dermatologist or prescriber with a specialty in dermatology
- Continued coverage is dependent on evidence of improvement, specifically:
  - ≥75% reduction in the Psoriasis Area and Severity Index (PASI) score, OR
  - ≥50% reduction in PASI with a ≥5 point improvement in DLQI (Dermatology Life Quality Index), OR
  - Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Skyrizi (risankizumab)	75mg/ 0.83mL Pre-filled Inj	02487454	DNP	E (SF)	ABV
Criteria	<b>Clinical Note:</b> <ul style="list-style-type: none"> <li>Treatment should be discontinued if a response has not been demonstrated by 16 weeks.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Probuphine (buprenorphine hydrochloride)	80mg Implant Kit	02474921	DN	E (SF)	KNI
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with opioid use disorder who have been stabilized on a daily dose of no more than 8mg of sublingual buprenorphine for the preceding 90 days.</li> </ul>				

### Criteria Update

The following criteria has been updated effective **immediately**:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kalydeco (ivacaftor)	150mg Tab	02397412	DNP	E (SF)	VTX
Criteria	<ul style="list-style-type: none"> <li>For the treatment of cystic fibrosis in patients who are:           <ul style="list-style-type: none"> <li>age 6 years and older and have one of the following cystic fibrosis transmembrane conductance regulator (CFTR) gene mutations: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R; or</li> <li>age 18 years and older with an R117H mutation in the CFTR gene.</li> </ul> </li> </ul>				

Criteria Update Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kalydeco (ivacaftor)	150mg Tab	02397412	DNP	E (SF)	VTX
Criteria	<p><b>Renewal criteria<sup>1</sup>:</b></p> <ul style="list-style-type: none"> <li>● Renewal requests will be considered in patients with documented response to treatment as evidenced by the following:           <ul style="list-style-type: none"> <li>○ In cases where the baseline sweat chloride levels were greater than 60 mmol/L:               <ul style="list-style-type: none"> <li>▪ the patient's sweat chloride level fell below 60 mmol/L; or</li> <li>▪ the patient's sweat chloride level falls by at least 30%</li> </ul> </li> <li>○ In cases where the baseline sweat chloride levels were below 60 mmol/L:               <ul style="list-style-type: none"> <li>▪ the patient's sweat chloride level falls by at least 30%; or</li> <li>▪ the patient demonstrates a sustained absolute improvement in FEV<sub>1</sub> of at least 5% when compared to the FEV<sub>1</sub> test conducted prior to starting therapy. FEV<sub>1</sub> will be compared with the baseline pre-treatment level one month and three months after starting treatment</li> </ul> </li> </ul> </li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>● The patient's sweat chloride level and FEV<sub>1</sub> must be provided with each request.</li> <li>● A sweat chloride test must be performed within a few months of starting ivacaftor therapy to determine if sweat chloride levels are reducing.           <ul style="list-style-type: none"> <li>○ If the expected reduction occurs, a sweat chloride test must be performed again 6 months after starting therapy to determine if the full reduction has been achieved. Thereafter, sweat chloride levels must be checked annually.</li> <li>○ If the expected reduction does not occur, a sweat chloride test should be performed again one week later. If the criteria are not met, coverage will be discontinued.</li> </ul> </li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>● Approved dose: 150mg every 12 hours.</li> <li>● Approval period: 1 year.</li> </ul> <p><sup>1</sup>. It should be noted that, while baseline sweat chloride levels and FEV<sub>1</sub> are not required to meet initial approval criteria for ivacaftor, these parameters may be used to evaluate the effect of ivacaftor upon renewal of the request. It is important that the physician measures baseline sweat chloride levels and FEV<sub>1</sub> and provides this information upon renewal to avoid delays in the assessment of the renewal funding decision as these measurements may be required to evaluate renewal requests.</p>				

## Non-Insured Products

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Biktarvy	50mg/200mg/25mg Tab	02478579	N/A	<b>Not Insured</b>	GIL

The following product will not be insured in the Pharmacare Programs; however, it will be funded through the Exception Drug Fund.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Brineura	150mg/5mL	02484013	N/A	<b>Not Insured</b>	BMR

## Change in Benefit Status

Effective immediately, Lansoprazole Oral Suspension (PIN 00903192) will be a full benefit for patients 19 years and under.

## Criteria Codes for Prevacid FasTab 15mg and 30mg

Effective immediately, criteria codes have been added for the use of standard dose\* Prevacid FasTab 15mg and 30mg.

**[Criteria code 37]** For patients who require the use of a proton pump inhibitor and require administration through a feeding tube.

**[Criteria code 38]** For patients 19 years of age and younger, who require the use of a proton pump inhibitor and who cannot use a tablet or capsule.

**\*Maximum 425 tablets per year**

## Therapeutic Substitution Policy Update - Famotidine

Please be advised that the policy for Therapeutic Substitution has been updated to include situations in which a pharmacist is prescribing an alternative medication for Pharmacare beneficiaries who are affected by the famotidine shortage.

This temporary fee (limit one per patient) is only payable when a therapeutic substitution fee has NOT already been billed for ranitidine AND:

1. The patient is on a Schedule 1 medication (famotidine 40mg) OR
2. In situations where it is not feasible for the prescriber of the famotidine be contacted or for the patient to discuss with their original prescriber at an upcoming visit (including patients without a family physician).

Pharmacists must comply with all applicable Nova Scotia College of Pharmacists (NSCP) policies and standards. Standards of Practice for prescribing can be found at:

[https://www.nspharmacists.ca/wp-content/uploads/2016/05/SOP\\_PrescribingDrugs.pdf](https://www.nspharmacists.ca/wp-content/uploads/2016/05/SOP_PrescribingDrugs.pdf)

As part of the prescribing assessment, pharmacists are expected to assess whether continued gastric acid suppression is required and whether lifestyle modifications or other products such as antacids should be tried versus a prescription medication. Proton pump inhibitors (PPIs) may be an appropriate therapy for some patients. It is noted however that concerns regarding overprescribing of PPIs and associated side effects has been growing. For example, Choosing Wisely Canada (Recommendations from the Canadian Association of Gastroenterology) highlights that “even though GERD is often a chronic condition, over time the disease may not require acid suppression and it is important that patients do not take drugs that are no longer necessary. For this reason patients should try stopping their acid suppressive therapy at least once per year. Patients with Barrett’s esophagus, Los Angeles Grade D esophagitis, and gastrointestinal bleeding would be exempt from this”.

<https://choosingwiselycanada.org/gastroenterology/>

The Deprescribing Network also provides algorithms and evidence-based guidelines regarding appropriate use of proton pump inhibitors

<https://www.deprescribingnetwork.ca/>

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### Nova Scotia Formulary Updates

New Form for Oral Diabetes Treatments

New Exception Status Benefits

- Cubicin RF (daptomycin)
- Duodopa (levodopa/carbidopa)
- Glatect (glatiramer acetate)
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New Products

### Included with this bulletin

Request for Insured Coverage of Oral Antidiabetic Agents form

## Nova Scotia Formulary Updates

### New Form for Oral Diabetes Treatments

The request form for oral diabetes agents has been revised to provide clarity to coverage parameters, in particular when insulin is not an option. The new form also requires that prescribers provide the patient's most recent A1C.

The request form for second line therapy for patients at high cardiovascular risk remains the same.

The new form can found at the following link:

<https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp>

### New Exception Status Benefits

The following products have been listed with the following criteria, effective immediately.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cubicin RF (Daptomycin)	500mg/ 10mL Single- Use Vial	02465493	DNP	E (SFC)	SNV
Criteria	<ul style="list-style-type: none"><li>• For the treatment of patients with resistant gram-positive infections, including methicillin-resistant Staphylococcus aureus (MRSA) who failed to respond, or have a contraindication or intolerance to vancomycin, or for whom IV vancomycin is not appropriate.</li></ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"><li>• Daptomycin is inhibited by pulmonary surfactant and should not be used to treat respiratory tract infections.</li></ul> <p><b>Claim Note:</b></p> <ul style="list-style-type: none"><li>• Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.</li></ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Duodopa (levodopa/ carbidopa)	20mg/5mg Intestinal Gel Cassettes	02292165	DNP	E (SF)	ABV
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of patients with advanced levodopa-responsive Parkinson's Disease (PD) who meet all of the following criteria:               <ul style="list-style-type: none"> <li>○ Experiences severe disability with at least 25% of the waking day in the off state and/or ongoing levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day).</li> <li>○ Have received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response.</li> <li>○ Have failed an adequate trial of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgment of prescriber: entacapone, a dopamine agonist, a monoamine oxidase-B (MAO-B) inhibitor and amantadine.</li> <li>○ Must be able to administer the medication and care for the administration port and infusion pump. Alternatively, trained personnel or a care partner must be available to perform these tasks reliably.</li> </ul> </li> </ul> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>• Patients with a contraindication to the insertion of a PEG-J tube.</li> <li>• Patients with severe psychosis or dementia.</li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>• Patients continue to demonstrate a significant reduction in the time spent in the off state and/or in ongoing levodopa-induced dyskinesias, along with and an improvement in the related disability.</li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>• Time in the off state, frequency of motor fluctuations, and severity of associated disability should be assessed by a movement disorder subspecialist and be based on an adequate and reliable account from longitudinal specialist care, clinical interview of a patient and/or care partner, or motor symptom diary.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>• Must be prescribed by a movement disorder subspecialist who has appropriate training in the use of Duodopa and is practicing in a movement disorder clinic that provides ongoing management and support for patients receiving treatment with Duodopa.</li> <li>• Approval period: 1 year.</li> </ul>				



New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Glatect</b> (glatiramer acetate)	20mg Pre-Filled Syringe	02460661	DNP	E (SF)	PDP
Criteria	<p><b>For glatiramer acetate-naïve patients whose glatiramer acetate therapy is initiated after April 1, 2020, the Glatect brand will be the product approved.</b></p> <p>Prescribed by a neurologist with experience in the treatment of multiple sclerosis for patients who meet the following criteria:</p> <p><b>Treatment Initiation:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of Multiple Sclerosis with a relapsing course*:             <ul style="list-style-type: none"> <li>○ Includes relapsing-remitting MS and secondary progressive MS with clear superimposed relapses;</li> <li>○ Does not include primary progressive MS, progressive-relapsing or secondary progressive MS without relapses;</li> </ul> <p style="text-align: center;"><u>and</u></p> <li>○ Disability judged to be equivalent to Expanded Disability Status Score (EDSS) of 5.5 or less (exceptions are permitted in special cases).</li> </li></ul> <p><b>Renewal:</b></p> <ul style="list-style-type: none"> <li>• EDSS not greater than 6.0 for at least 12 months in the absence of relapses.</li> <li>• Patients must be assessed for compliance and for any therapy related side effects that are intolerable.</li> </ul> <p><b>Exclusions:</b></p> <ul style="list-style-type: none"> <li>• Concurrent illness likely to alter compliance or substantially reduce life expectancy</li> </ul> <p>* Relapsing course is defined as evidence of one relapse in the past 18 months or two relapses in the past 3 years.</p>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Tygacil</b> (tigecycline)	50mg Vial	02285401	DNP	E (SFC)	PFI
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of patients with multi-drug resistant infections when alternative agents are not an option.</li> </ul> <p><b>Claim Note:</b></p> <ul style="list-style-type: none"> <li>• Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.</li> </ul>				



New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Zerbaxa</b> (ceftolozane/ tazobactam)	1g/0.5g Vial	02446901	DNP	E (SFC)	FRS
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with multidrug-resistant gram-negative infections, specifically caused by extended spectrum beta lactamase (ESBL)-producing Enterobacteriaceae and multidrug-resistant Pseudomonas aeruginosa when alternative agents are not an option.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Must be prescribed by, or in consultation with, an infectious disease specialist or medical microbiologist.</li> </ul>				

## New Products

Effective **immediately**, the following new products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
AmBisome	50mg/Vial	02241630	DNP	SFC	GIL
Cancidas IV	50mg Pwd for Inj	02244265	DNP	SFC	FRS
Cancidas IV	70mg Pwd for Inj	02244266	DNP	SFC	FRS
Fulvestant	50mg/mL	Various	DNP	SFC	VAR
pms-Fluoxetine	40mg Cap	02464640	DNP	SFC	PMS
pms-Fluoxetine	60mg Cap	02464659	DNP	SFC	PMS



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### **Nova Scotia Formulary Updates**

Public Funding for Prescription  
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Effective March 19, 2020

In-Person Requirement Waived for  
Assessment and Prescribing

Adjustment to Days Supply for  
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Beneficiaries During COVID-19  
Outbreak

### **Nova Scotia Formulary Updates**

#### **Public Funding for Prescription Renewal Services Available Effective March 19, 2020**

To make it easier for Nova Scotians to renew prescriptions if required during the current COVID-19 outbreak, effective March 19, 2020, the Department of Health & Wellness will begin covering the professional service fee for pharmacists to prescribe prescription renewals for all eligible residents with a valid Nova Scotia health card.

This is earlier than the original launch date of April 1, 2020. The cost will be covered in accordance with the *Pharmacy Service Agreement*, which establishes fees of \$12 if three or fewer prescriptions are renewed during the service encounter, and \$20 if four or more prescriptions are renewed. Residents will continue to access their usual drug coverage or method of payment for any prescriptions they have filled.

As a temporary measure during the outbreak, and until June 1, 2020, there will be no claim limit (cap) on the number of prescription renewal services that can be billed for an eligible resident. Other than the cap being lifted, all other requirements as identified in the ***Nova Scotia Pharmacy Guide*** will apply for service claims.

Prescription renewals do **not** need to be completed in person.

#### **In-Person Requirement Waived for Assessment and Prescribing**

To support social distancing and residents in self isolation, the requirement for a patient to meet with a pharmacist for an in-person assessment for a funded clinical service is temporarily waived effective immediately and until June 1, 2020.

Pharmacists should refer to their Standards of Practice and use their professional discretion to determine if a service should be provided without an in-person assessment. All other requirements as identified in the ***Nova Scotia Pharmacy Guide*** will continue to apply for service claims.

## **Adjustments to Days Supply for Dispensing to Pharmacare Beneficiaries During COVID-19 Outbreak**

As a temporary measure, based on recommendations from the Nova Scotia College of Pharmacists, the Nova Scotia Pharmacare Programs will accept dispensing of smaller quantities than prescribed for all medications for a supply not lower than 30 days. Verbal order documentation requirements will not apply for prescriptions modified to the lower days supply in keeping with this recommendation during this time.

If there is a confirmed and severe specific drug shortage, exemptions may be granted for less than 30 days supply and exemptions to the 28-day supply list in the Nova Scotia Pharmacy Guide. Any such exemptions will be communicated to pharmacies.

**Any changes to the above measures will be communicated to pharmacies through this bulletin.**



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### **Nova Scotia Formulary Updates**

Extension of Coverage for  
Exception Status Medications

New Exception Status Benefits

- Ocrevus (ocrelizumab)
- Fulphila (pegfilgrastim)
- Lapelga (pegfilgrastim)

Criteria Update

- Tafinlar (dabrafenib) and  
Mekinist (trametinib)

### **Nova Scotia Formulary Updates**

#### **Extension of Coverage for Exception Status Medications**

To support Nova Scotia residents and healthcare providers during the COVID-19 pandemic and to ensure Pharmacare beneficiaries have continued access to specific medications, the following changes are effective immediately:

- Approvals for coverage of exception status drugs that will be expiring before July 1, 2020 will be extended for an additional three months. For example, requests expiring May 23<sup>rd</sup> will now expire August 23<sup>rd</sup>. In addition, those that expired in February and have not already been renewed, have been extended to July 1, 2020.
- Usual quantity limits for biologics will continue to apply as per specific coverage criteria limits.
- This change applies to renewals for coverage. New requests for coverage should continue to be submitted as per usual processes.

## New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Ocrevus (ocrelizumab)	300mg/10mL Vial	02467224	DNP	E (SF)	HLR
Criteria	<p><b>Primary Progressive Multiple Sclerosis</b></p> <ul style="list-style-type: none"> <li>For the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) who meet all of the following criteria:             <ul style="list-style-type: none"> <li>Confirmed diagnosis based on McDonald criteria</li> <li>Recent Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5</li> <li>Recent Functional Systems Scale (FSS) score of at least 2 for the pyramidal functions component due to lower extremity findings</li> <li>Disease duration of 10 years for those with an EDSS of less than or equal to 5 or disease duration less than 15 years for those with an EDSS greater than 5</li> <li>Diagnostic imaging features characteristic of inflammatory activity</li> <li>Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.</li> </ul> </li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.</li> </ul> <p><b>Relapsing Remitting Multiple Sclerosis</b></p> <ul style="list-style-type: none"> <li>For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria:             <ul style="list-style-type: none"> <li>Confirmed diagnosis based on McDonald criteria</li> <li>Experienced one or more disabling relapses or new MRI activity in the last two years</li> <li>Are fully ambulatory without aids (i.e., must provide a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 5.5)</li> <li>Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.</li> </ul> </li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>Treatment should be discontinued for patients with an EDSS score of greater than or equal to 6.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.</li> <li>Claims for Ocrevus 300mg/10mL Vial that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN:             <ul style="list-style-type: none"> <li>00904527</li> </ul> </li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Fulphila</b> (pegfilgrastim)	6mg/0.6mL (10mg/mL) PF Sol for Inj	02484153	DNP	E (SFC)	BGP
<b>Lapelga</b> (pegfilgrastim)	6mg Pre-filled Syringe	02474565	DNP	E (SFC)	APX
Criteria	<ul style="list-style-type: none"> <li>For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who: <ul style="list-style-type: none"> <li>are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; or</li> <li>have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or</li> <li>have had a dose reduction, or treatment delay greater than one week due to neutropenia.</li> </ul> </li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.</li> </ul>				

### Criteria Update

The following criteria has been updated effective **immediately**:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Tafinlar</b> (dabrafenib)	50mg Cap	02409607	DNP	E (SFC)	NVR
	75mg Cap	02409615	DNP	E (SFC)	NVR
<b>Mekinist</b> (trametinib)	0.5mg Tab	02409623	DNP	E (SFC)	NVR
	2mg Tab	02409658	DNP	E (SFC)	NVR
Criteria	<ul style="list-style-type: none"> <li>Dabrafenib-trametinib combination therapy as a first-line BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.</li> <li>In the event that a patient is initiated on dabrafenib-trametinib combination therapy and has to discontinue one agent due to toxicity, dabrafenib or trametinib monotherapy as a first-line BRAF-mutation targeted treatment for patients with BRAF V600 mutation positive, unresectable or metastatic melanoma and who have an ECOG performance status of 0 or 1, will be funded, should that be the chosen treatment option. Treatment should continue until disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms. For clarity, initiation of treatment with dabrafenib or trametinib monotherapy will not be funded.</li> <li>For the adjuvant treatment of patients with stage IIIA (limited to lymph node metastases of &gt; 1 mm) to stage IIID (8th edition of American Joint Committee on Cancer [AJCC])</li> </ul>				

Criteria Update Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Tafinlar</b> (dabrafenib)	50mg Cap	02409607	DNP	E (SFC)	NVR
	75mg Cap	02409615	DNP	E (SFC)	NVR
<b>Mekinist</b> (trametinib)	0.5mg Tab	02409623	DNP	E (SFC)	NVR
	2mg Tab	02409658	DNP	E (SFC)	NVR
Criteria	<p>staging system) BRAF-mutated (all BRAF V600 mutations) cutaneous melanoma. Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed.</p> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Patients should have a good performance status.</li> <li>• Treatment with dabrafenib plus trametinib should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.</li> <li>• Patients are eligible to receive 12 months of adjuvant treatment with immunotherapy or BRAF targeted therapy. Patients who are unable to tolerate initial adjuvant therapy, within the first 3 months of treatment, may switch to alternate funded treatment, provided criteria are met.</li> <li>• Patients with mucosal or ocular melanoma are not eligible for treatment with dabrafenib/trametinib.</li> <li>• Patients who relapse during, or at any time after adjuvant dabrafenib/trametinib therapy, are eligible for treatment with combination immunotherapy (i.e. nivolumab with ipilimumab) in the metastatic setting. Patients who are not candidates for combination immunotherapy are eligible for single agent nivolumab or pembrolizumab immunotherapy in the metastatic setting.</li> <li>• Re-treatment with BRAF targeted therapy is funded if the treatment-free interval is <math>\geq 6</math> months from the completion of adjuvant BRAF therapy.</li> </ul>				





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### **Nova Scotia Formulary Updates**

Coverage of Extra Dispensing Fees

## **Nova Scotia Formulary Updates**

### **Coverage of Extra Dispensing Fees**

#### **Pharmacare coverage of extra costs associated with the 30-day prescription supply recommendation**

To address the additional out-of-pocket costs some Pharmacare beneficiaries may incur when their prescription supplies are reduced in accordance with the Nova Scotia College of Pharmacists' recommendation to limit prescription supplies to 30 days during the COVID-19 pandemic, the following changes have been made, effective April 23, 2020.

#### **Department of Community Services Pharmacare Benefits clients**

For clients enrolled in the Department of Community Services (DCS) Pharmacare Benefits program, DCS will be waiving the \$5 copay on all prescriptions starting April 23, 2020. Pharmacies must bill the usual dispensing fee for these claims and the copay will be adjusted to \$0 during adjudication.

#### **Seniors' and Family Pharmacare Program clients who are financially affected by a reduction in their usual days supply of medication**

For Pharmacare beneficiaries who would have filled a particular prescription for more than 30 days, and the quantity is being reduced because of the current recommendation, pharmacists are asked to remove the dispensing fee on any "extra" claims billed so that this fee will not be included in the calculation of the patient's copayment. For example:

- For a typical supply of 60 days, enter a dispensing fee of \$0 for the **second** refill only.
- For a typical supply of 90 days, enter a dispensing fee of \$0 for the **second** and **third** refills only.

The usual full dispensing fee must be billed when the patient would normally have filled their prescription (e.g. one dispensing fee every 60 or 90 days, the first fill of a new prescription, etc.).

**Coverage of Extra Dispensing Fees Continued...**

This approach can also be used for clients who rely solely on the Family Pharmacare Program as their drug insurance, including before they have met their deductible. It cannot be used when the client also has another form of drug insurance and Family Pharmacare is the second payer.

To ensure pharmacies are fully compensated for the dispensing fees that were not charged, a bottom-line adjustment will be applied on each pharmacy's Pharmacare payment based on their usual and customary dispensing fee for those claims that were billed as \$0. For example, if a pharmacy submitted 100 claims with a \$0 dispensing fee, and the pharmacy's usual dispensing fee is the Pharmacare maximum of \$12.25, the pharmacy will automatically receive an additional \$1,225 as part of their Pharmacare payment. These payments will appear on biweekly statements; however, it is estimated these payments may be delayed by two weeks versus the online portion of the claim. Adjusted payments will commence approximately 3-4 weeks from now.

It is important that this approach be used as accurately as possible, based on the pharmacy staff's review of the patient's prescription records, copayment history and dispensing history in order to determine the patient's eligibility for the \$0 dispensing fee.

This coverage will remain in effect until June 30, 2020, or until an earlier date should the recommendation from the College of Pharmacists be lifted prior to June 30. Any change in end date for the coverage will be communicated to pharmacies through this bulletin.

If specific Pharmacare beneficiaries are concerned that they have already been financially affected by refills after April 1st and before the effective date of this policy, please direct them to contact Pharmacare at 1-800-305-5026 to review their situation.

**Billing for Seniors' and Family Pharmacare Program clients who have not been financially affected by a reduction in their usual days supply of medication**

Claims for Pharmacare beneficiaries who are not affected financially by the 30-day supply recommendation should be billed as usual. For example:

- If an eligible Pharmacare beneficiary typically filled their prescription for a supply of 30 days or less, the claim should be billed as usual including the dispensing fee.
- If a client of any Pharmacare Program is already copay exempt, their claims should be billed as usual including the dispensing fee. This would include seniors and members of Family Pharmacare who do not pay copayment at the pharmacy or who are now copay exempt.

While we understand this approach will require the additional attention of the pharmacy staff to ensure appropriate adjudication, and a delay in the payment of some dispensing fees, it allows for immediate financial relief for Pharmacare beneficiaries at the pharmacy counter and a mechanism for government to absorb 100% of the additional costs. Along with other stakeholders, we support the lifting of the 30-day recommendation as soon as can be appropriately implemented.



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### **Nova Scotia Formulary Updates**

Update on COVID-19 Pharmacy Measures

## **Nova Scotia Formulary Updates**

### **Update on COVID-19 Pharmacy Measures**

#### **Pharmacare Update on 30-day Prescription Limits**

As drug supplies and pharmacist management of drug shortages is normalizing, the following changes are in effect immediately for Pharmacare claims:

Extra dispensing fees related to the Nova Scotia College of Pharmacists 30-day supply directive will continue to be absorbed by the Seniors' and Family Pharmacare Programs on previously affected prescriptions for the patient's next refill, when the balance of the prescription owing is expected to be provided. As most beneficiaries will have received balance of their prescription at the next refill, the option of covering the additional dispensing fee portion of the copayment for beneficiaries (i.e. entering \$0 in the dispensing fee field) will not be available after June 30, 2020.

For clients enrolled in the Department of Community Services (DCS) Pharmacare Benefits program, DCS will continue to waive the \$5 copay on all prescriptions until further notice.

Effective immediately, any reduction of supplies dispensed that are not in accordance with the supply requested by the prescriber must follow normal pre-COVID 19 practices and are subject to audit as per the ***Nova Scotia Pharmacy Guide***.

#### **Removal of In-Person Requirement for Assessment and Prescribing and Claim Limits on Renewals – Extended to June 30, 2020**

In the March bulletin, pharmacies were advised that the in-person requirement for assessment and prescribing (contraceptive management, urinary tract infection, herpes zoster) was removed as well as the removal of the per-person claim limit for prescription renewals, until June 1, 2020. This should have read June 30, 2020.

Pharmacists should refer to their Standards of Practice and use their professional discretion to determine if a service should be provided without an in-person assessment. All other requirements as identified in the ***Nova Scotia Pharmacy Guide*** will continue to apply for service claims.

**Update on COVID-19 Pharmacy Measures Continued...**

**New Benefit - UK Labelled Teva-Salbutamol**

Teva Canada Limited has received approval from Health Canada for the importation and release of a limited supply of UK-labelled salbutamol metered dose inhalers to mitigate the shortages of salbutamol MDIs in Canada related to the COVID-19 pandemic.

The Nova Scotia Pharmacare Programs will be adding this product as a temporary benefit effective May 21, 2020.

The UK-labelled salbutamol inhalers have the same active ingredient and concentration as the Canadian product and are used in the same way. However, there are differences in the preparation for use instructions and labelling regarding maximum doses. Pharmacists are directed to consult and use the Health Canada information available at <https://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73095a-eng.php> when prescribing or dispensing this product.

PRODUCT	STRENGTH	PIN	PRESCRIBER	BENEFIT STATUS	MFR
Teva-Salamol CFC-Free 100mcg	100mcg/dose oral inhaler	09858115	DNPM	SFC	TEV



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New Product

## Nova Scotia Formulary Updates

### Receiving Patient-Related Correspondence

Pharmacists who prescribe in Nova Scotia must register with Medavie to be eligible as a prescriber under the Pharmacare programs. The “Main Address” submitted with your registration will be used for all patient correspondence that Medavie sends you as the prescriber. **This address must be accurate and appropriate for receiving and handling private patient information.**

An example of a patient-related correspondence you would receive is if you submitted an exception status drug request as the prescriber of a medication. Your Main Address will be used even if you provided a different address on the request form.

You are responsible under the Personal Health Information Act to ensure the patient information sent to your Main Address is protected from unauthorized disclosure or use. **If you need to change your address**, please visit <https://www.medaviebc.ca/en/health-professionals/register> to update your profile information.

### Use of Specific Prescriber Numbers

Pharmacists are reminded that all claims submitted for pharmacist-prescribed drugs and pharmacy services must be submitted with the prescribing pharmacist's NSCP licence number, not a default ID (e.g. 7111). All pharmacists delivering publicly funded assessment and prescribing services in Nova Scotia **must be registered with Medavie as a prescriber** prior to submitting claims for pharmacy services. Registration can be completed online at: <https://www.medaviebc.ca/en/health-professionals/register>

## New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Sublocade (buprenorphine)</b>	100mg/0.5mL	02483084	DN	E (SF)	ICL
	300mg/1.5mL	02483092	DN	E (SF)	ICL
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with opioid use disorder who have been stabilized on a dose of 8 mg to 24 mg per day of sublingual buprenorphine for a minimum of seven days.</li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>The patient must be under the care of a prescriber certified under the Sublocade Certification Program.</li> </ul> <p><b>Claim Note:</b></p> <ul style="list-style-type: none"> <li>Approvals will be for one prefilled syringe per month.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Cotellic (cobimetinib)</b>	20mg Tab	02452340	DNP	E (SFC)	HLR
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used in combination with vemurafenib.</li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>If brain metastases are present, patients should be asymptomatic or have stable symptoms.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Cobimetinib will not be reimbursed in patients who have progressed on BRAF and/or MEK inhibitor therapy.</li> </ul>				



New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Cabometyx (cabozantinib)	20mg Tab	02480824	DNP	E (SFC)	IPS
	40mg Tab	02480832	DNP	E (SFC)	IPS
	60mg Tab	02480840	DNP	E (SFC)	IPS
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with advanced or metastatic renal cell carcinoma (RCC) who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy. Treatment may continue until clinically meaningful disease progression or unacceptable toxicity.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients with any histology (clear cell or non-clear cell) and IMDC risk are eligible.</li> <li>For patients treated with a VEGF-TKI (sunitinib or pazopanib) first-line, cabozantinib may be used as either a second or third-line treatment option. If cabozantinib is used as second-line therapy, nivolumab may be used as third-line therapy or vice-versa.</li> <li>For patients treated with nivolumab + ipilimumab first-line and VEGF TKI (sunitinib or pazopanib) second-line, either cabozantinib or axitinib may be used as third-line therapy.</li> <li>Sequential use of cabozantinib and axitinib (as a single agent) is not funded except in the case of intolerance or contraindication.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xeljanz XR (tofacitinib)	11mg XR Tab	02470608	DNP	E (SF)	PFI
Criteria	<ul style="list-style-type: none"> <li>For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:             <ul style="list-style-type: none"> <li>methotrexate (oral or parenteral) at a dose of <math>\geq 20</math>mg weekly (<math>\geq 15</math>mg if patient is <math>\geq 65</math> years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks; OR</li> <li>initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs such as hydroxychloroquine and sulfasalazine, for a minimum of 24 weeks.</li> </ul> </li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.</li> <li>Optimal treatment response may take up to 24 weeks; however coverage of tofacitinib can be considered if no improvement is seen after 12 weeks of triple DMARD use.</li> <li>If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.</li> </ul>				



New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Xeljanz XR (tofacitinib)</b>	11mg XR Tab	02470608	DNP	E (SF)	PFI
Criteria	<ul style="list-style-type: none"> <li>Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.</li> <li>Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.</li> <li>Must be prescribed by a rheumatologist.</li> <li>Combined use with biologic DMARD will not be reimbursed</li> </ul>				

### Criteria Updates

The following criteria has been updated effective **immediately**:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Tagrisso (osimertinib)</b>	40mg Tab	02456214	DNP	E (SFC)	AZE
	80mg Tab	02456222	DNP	E (SFC)	AZE
Criteria	<ul style="list-style-type: none"> <li>For the first-line treatment of patients with locally advanced (not amenable to curative-intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumors have the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletions [exon 19 del] or exon 21 [L858R] mutations. Eligible patients should be previously untreated in the locally advanced or metastatic setting and have a good performance status. Treatment may continue until clinically meaningful disease progression or unacceptable toxicity.</li> <li>For the treatment of patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC) who have progressed on EGFR tyrosine kinase inhibitor (TKI) therapy, or as initial therapy in patients with a <i>de novo</i> EGFR T790M mutation.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients currently receiving alternate first-line EGFR TKI's (e.g. erlotinib, gefitinib, afatinib) whose tumors have the noted EGFR mutations (exon 19 del or L858R) may be switched to osimertinib provided they meet all other funding criteria and have not experienced disease progression.</li> <li>Patients who have initiated treatment with chemotherapy prior to receiving results of the EGFR mutation status may be switched to osimertinib if otherwise eligible.</li> <li>Osimertinib may be continued until there is evidence of disease progression or the development of unacceptable toxicity.</li> </ul>				

**Criteria Updates Continued...**

The following indication has been added to existing criteria **effective immediately**:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zelboraf (vemurafenib)	240mg Tab	02380242	DNP	E (SFC)	HLR
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with cobimetinib.</li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>If brain metastases are present, patients should be asymptomatic or have stable symptoms.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul> <p><b>Claim Note:</b></p> <ul style="list-style-type: none"> <li>Vemurafenib will not be reimbursed in patients who have progressed on BRAF and/or MEK inhibitor therapy.</li> </ul>				

**New Product**

Effective **immediately**, the following new product has been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Izba	0.003% Oph Sol	02457997	DNP	SF	NVR

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New Diabetic Product

### Nova Scotia Formulary Updates

#### Reinstating Prescription Renewal Limits

As a temporary measure during the COVID-19 outbreak, the claim limit (cap) on the number of prescription renewal services that can be billed for an eligible resident was removed. As access to the health care system is normalizing, the claim limit (cap) on the number of prescription renewals will be reinstated as of July 15, 2020. The claim limit for each resident will be reset on July 15, 2020.

To enable the claim limit to be reset, new PINS have been assigned to the prescription renewal claims and will be effective as of July 15, 2020 when the previous PINs will no longer be valid.

	PIN VALID MAR 19 TO JULY 14, 2020	PIN VALID JULY 15, 2020 ONWARDS
3 or less eligible prescriptions are renewed	93899860	93899846
4 or more eligible prescriptions are renewed	93899859	93899845

Pharmacists are reminded to determine, when completing the patient assessment, if there are likely to be other prescriptions that will require renewal within a reasonable timeframe and provide those renewals at the same time. This will ensure that the patient is able to receive optimal benefit for this service. It is not appropriate to bill for sequential use of the PINS within a short time frame when the renewals reasonably could have been done at the same time. For clarity, as described in the Pharmacy Guide, the claim limit (cap) is as follows:

- A maximum of four (4) prescription renewal PINs of any combination per resident within a one-year period. For example, three claims for one PIN and one for the other PIN, or two claims for each PIN.

## Removal of In-Person Requirement for Assessment and Prescribing – Extended to September 30, 2020

The removal of the requirement to do an in-person assessment for assessing and prescribing for a urinary tract infection, herpes zoster, and contraceptive management has been extended until September 30<sup>th</sup>. Pharmacists should refer to their Standards of Practice and use their professional discretion to determine if a service should be provided without an in-person assessment. All other requirements as identified in the Nova Scotia Pharmacy Guide will continue to apply.

## Change in Billing Process for Therapeutic Substitution and Prescription Adaptation Services

When pharmacists provide Therapeutic Substitution and Prescription Adaptation (including Refusal to Fill) services for Pharmacare beneficiaries, the current Pharmacare billing process requires that a claim for the original prescribed drug be submitted then reversed. Effective immediately, this step is no longer required. No claim for the original drug needs to be submitted. However, the claim for the substituted or adapted prescription product should continue to be billed on the same day as the service claim. This change to the billing process will be reflected in the next update to the Pharmacy Guide.

## New Benefit - Spanish Labelled JAMP-Salbutamol

JAMP Pharma Corporation has received approval from Health Canada for the importation and release of a limited supply of Spanish-labelled salbutamol metered dose inhalers to mitigate the shortages of salbutamol MDIs in Canada related to the COVID-19 pandemic.

The Nova Scotia Pharmacare Programs will be adding this product as a temporary benefit effective **immediately**.

The Spanish-labelled salbutamol inhalers have the same active ingredient and concentration as the Canadian product and are used in the same way. However there are differences, including preparation for use instructions. Pharmacists are directed to consult and use the Health Canada information available at <https://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73143a-eng.php> when prescribing or dispensing this product.

PRODUCT	STRENGTH	PIN	PRESCRIBER	BENEFIT STATUS	MFR
Jamp-Salbutamol Aldo-Union	100mcg	09858116	DNPM	SFC	JPC

## New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Erleada (apalutamide)</b>	60mg Tab	02478374	DNP	E (SFC)	JAN
Criteria	<ul style="list-style-type: none"> <li>In combination with androgen deprivation therapy (ADT) for the treatment of patients with castration-resistant prostate cancer (CRPC) who have no detectable distant metastasis (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases<sup>1</sup>.</li> <li>Patients should have a good performance status and no risk factors for seizures. Treatment should continue until unacceptable toxicity or radiographic disease progression.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA &gt; 2 ng/mL.</li> <li>Castrate levels of testosterone must be maintained.</li> <li>Patients with N1 disease, pelvic lymph nodes &lt; 2cm in short axis located below the common iliac vessels are eligible for apalutamide.</li> <li>Apalutamide will not be funded for patients who experience disease progression on enzalutamide.</li> <li>Patients receiving apalutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on apalutamide.</li> <li>Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued apalutamide in the non-metastatic setting due to intolerance without disease progression.</li> </ul> <p>1. High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT</p>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Radicava (edaravone)</b>	30mg/100mL IV Inj	02475472	DNP	E (SF)	MBT
Criteria	<p>For the treatment of amyotrophic lateral sclerosis (ALS), if the following criteria are met:</p> <p><b>Initiation Criteria</b></p> <ul style="list-style-type: none"> <li>Patient with a diagnosis of probable ALS or definite ALS; AND</li> <li>Patient who meets all of the following: <ul style="list-style-type: none"> <li>has scores of at least two points on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R)</li> <li>has a forced vital capacity greater than or equal to 80% of predicted</li> </ul> </li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Radicava (edaravone)</b>	30mg/100mL IV Inj	02475472	DNP	E (SF)	MBT
Criteria	<ul style="list-style-type: none"> <li>○ has had ALS symptoms for two years or less</li> <li>○ patient is not currently requiring permanent non-invasive or invasive ventilation.</li> </ul> <p><b>Renewal Criteria</b></p> <ul style="list-style-type: none"> <li>● Reimbursement of treatment should be discontinued in patients who meet any one of the following criteria: <ul style="list-style-type: none"> <li>○ patient becomes non-ambulatory (ALSFRS-R score <math>\leq</math> 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRS-R score <math>&lt;</math> 1 for item 5a or 5b);</li> <li>OR</li> <li>○ patient requires permanent non-invasive or invasive ventilation.</li> </ul> </li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>● Patient must be under the care of a specialist with experience in the diagnosis and management of ALS.</li> <li>● Claims for Radicava 30mg/100mL IV Injection that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN: <ul style="list-style-type: none"> <li>○ 00904538</li> </ul> </li> </ul>				

### Criteria Updates

The following criteria has been updated effective **immediately**:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Afinitor (everolimus)</b>	2.5mg Tab	02369257	DNP	E (SFC)	NVR
	5mg Tab	02339501	DNP	E (SFC)	NVR
	10mg Tab	02339528	DNP	E (SFC)	NVR
Criteria	<ul style="list-style-type: none"> <li>● For the treatment of patients with advanced or metastatic renal cell carcinoma following disease progression on tyrosine kinase inhibitor therapy.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>● Patients must have a good performance status.</li> <li>● Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> <li>● Requests for everolimus will not be considered for patients who experience disease progression on axitinib, cabozantinib or nivolumab monotherapy.</li> </ul>				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Fibristal (ulipristal acetate)</b>	5mg Tab	02408163	DNP	E (F)	ALL
Criteria	<ul style="list-style-type: none"> <li>For the treatment of adult women of reproductive age with moderate to severe uterine fibroids as either: <ul style="list-style-type: none"> <li>Pre-operative treatment in patients who are eligible for surgery;</li> <li>OR</li> <li>Intermittent treatment in patients who are not eligible for surgery.</li> </ul> </li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>Each course of treatment is three months in duration.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>The maximum quantity reimbursed is limited to four courses of treatment.</li> <li>The patient must be under the care of a physician experienced in the management of gynecological conditions such as uterine fibroids.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Inlyta (axitinib)</b>	1mg Tab 5mg Tab	02389630 02389649	DNP DNP	E (SFC) E (SFC)	PFI PFI
Criteria	<ul style="list-style-type: none"> <li>As second-line therapy for the treatment of patients with advanced or metastatic renal cell carcinoma (RCC), after failure of first-line tyrosine kinase inhibitor therapy.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>As third-line therapy for the treatment of patients with advanced or metastatic renal cell carcinoma (RCC), after failure of first-line immunotherapy, and second-line tyrosine kinase inhibitor therapy.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> <li>Sequential use of axitinib and everolimus is not permitted except in the case of intolerability or contraindication.</li> <li>For patients treated with nivolumab + ipilimumab first-line and VEGF TKI (sunitinib or pazopanib) second line, either cabozantinib <b>or</b> axitinib may be used as third-line therapy.</li> <li>Sequential use of cabozantinib and axitinib (as a single agent) is not funded except in the case of intolerance or contraindication.</li> <li>Both clear cell and non-clear cell histology are eligible for treatment.</li> </ul>				



Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Nexavar (sorafenib)</b>	200mg Tab	02284227	DNP	E (SFC)	BAY
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with advanced or metastatic renal cell carcinoma when used as a second-line therapy following disease progression on cytokine therapy.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Sutent (sunitinib)</b>	12.5mg Cap	02280795	DNP	E (SFC)	PFI
	25mg Cap	02280809	DNP	E (SFC)	PFI
	50mg Cap	02280817	DNP	E (SFC)	PFI
Criteria	<ul style="list-style-type: none"> <li>For patients with advanced or metastatic renal cell carcinoma as either first-line therapy, or second-line therapy after failure of first-line immunotherapy.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> <li>Sunitinib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib, or pazopanib) as sequential therapy.</li> <li>In the event of significant toxicity, a switch to another tyrosine kinase inhibitor (i.e., sorafenib or pazopanib) may be allowed.</li> <li>Both clear cell and non-clear cell histology are eligible for treatment.</li> </ul>				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Venclexta</b> (venetoclax)	10mg Tab	02458039	DNP	E (SFC)	ABV
	50mg Tab	02458047	DNP	E (SFC)	ABV
	100mg Tab	02458055	DNP	E (SFC)	ABV
	Starter Pack	02458063	DNP	E (SFC)	ABV
Criteria	<ul style="list-style-type: none"> <li>In <b>combination</b> with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy, irrespective of their 17p deletion status. Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of two years, whichever comes first.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients who were previously treated with and responded to an anti-CD20 therapy (rituximab or obinutuzumab) will be eligible for treatment with the combination of venetoclax plus rituximab if they had a progression-free interval of 12 months or longer.</li> <li>Patients currently receiving and responding to venetoclax monotherapy, and who have not achieved an adequate response are eligible to have rituximab added to venetoclax. Note: Venetoclax therapy is funded to a maximum of two years from the time rituximab is added.</li> <li>Patients may be retreated with venetoclax plus rituximab if they responded to and completed two years of therapy with at least 12 months of progression-free interval.</li> <li>Patients will be eligible for treatment with either ibrutinib, or idelalisib with rituximab following progression on venetoclax with rituximab if they have not received before and otherwise meet eligibility criteria.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Votrient</b> (pazopanib)	200mg Tab	02352303	DNP	E (SFC)	NVR
Criteria	<ul style="list-style-type: none"> <li>For patients with advanced or metastatic renal cell carcinoma as either first-line therapy, or second-line therapy after failure of first-line immunotherapy.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Patients must have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> <li>Pazopanib may not be used after another tyrosine kinase inhibitor (i.e., sorafenib, or sunitinib) as sequential therapy.</li> <li>In the event of significant toxicity, a switch to another tyrosine kinase inhibitor (i.e., sorafenib or sunitinib) may be allowed.</li> <li>Both clear cell and non-clear cell histology are eligible for treatment.</li> </ul>				

### New Diabetic Product

The following product is a new listing to the Nova Scotia Formulary, effective immediately. The benefit status within the Nova Scotia Pharmacare Programs is indicated.

PRODUCT	DIN/PIN	PRESCRIBER	BENEFIT STATUS	MFR
Droplet Micron Pen Needle 34G x 3.5mm	97799086	DNP	SFD	SFA



# PharmacareNEWS

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Updates to the Nova Scotia Pharmacy Guide

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## Nova Scotia Formulary Updates

### Updates to the Nova Scotia Pharmacy Guide

The Nova Scotia Pharmacy Guide has been updated and the latest version can be found online at: <https://novascotia.ca/dhw/pharmacare/pharmacy-guide.asp>

Updates include the following:

- In the **Administration** section, expanded information about the requirement for pharmacists to register with Medavie to be eligible as a prescriber for public drug and service claims (page 8).
- In the **Exception Status Drugs** section, new reference to pharmacists submitting requests as prescribers (page 24) and new requirements for using criteria codes (page 26).
- In the **Advanced Medication Review** section, requirement for pharmacies to register with PANS has been removed (page 29).
- In the **Therapeutic Substitution** and **Prescription Adaptation** sections, the requirement to submit and then reverse the original claim for the prescribed product has been removed (pages 32 and 34).
- In the section on **Administration of Publicly Funded Influenza Vaccinations by Pharmacists**, age requirement has been changed from 5 years to 2 years (page 37).
- In the section on **Assessment and Prescribing for Uncomplicated Cystitis, Herpes Zoster and Contraception Management**, new reference to the requirement that pharmacists must register with Medavie as a prescriber before conducting services (page 41). New reference that claims will not be accepted for assessment and prescribing of uncomplicated cystitis services if the patient is under 16 years old (page 41).
- In the **Prescription Renewal** section, new reference to the requirement that pharmacists must register with Medavie as a prescriber before conducting services (page 47) and new PINs effective July 15, 2020 (page 49).

**Updates to the Nova Scotia Pharmacy Guide Continued...**

- In the **Quantity Limits** section, addition of Xeljanz XR (page 56).
- In the **Audit** section, new reference that any potential falsification of prescription records identified during audit may be reported to the Nova Scotia College of Pharmacists (page 67) and new reference to implications of creating false verbal orders (page 69).

**New Exception Status Benefits**

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Elleyso (taliglucerase alfa)</b>	200U/Vial Pws for Inj	02425637	DNP	E (SF)	PFI
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of patients with symptomatic Gaucher disease type 1 (GD1) for whom treatment with velaglucerase alfa is not tolerated or contraindicated.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Velaglucerase alfa is the preferred reimbursed enzyme replacement therapy for GD1.</li> <li>• Requests for patients currently using taliglucerase alfa who do not have a contraindication or intolerance to velaglucerase alfa will be considered for coverage of velaglucerase alfa only.</li> <li>• Requests for coverage must meet the criteria for diagnosis of GD1, indication for therapy and expected response to enzyme replacement therapy outlined below:</li> </ul> <p><b>Initial Coverage</b></p> <p><b>Diagnosis</b></p> <ul style="list-style-type: none"> <li>• The diagnosis of GD1 must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.</li> <li>• Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD1 and not another condition that might mimic it.</li> <li>• The patient should not have any GD1-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD1, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely.</li> </ul> <p><b>Disease Severity</b></p> <p>Evidence of disease severity must be provided, and include at least one of the following:</p> <ul style="list-style-type: none"> <li>• <b>Hematological complications</b> <ul style="list-style-type: none"> <li>○ Hemoglobin &lt;85% of lower limit of age- and sex-appropriate normal after other causes of anemia, such as iron deficiency, have been treated or ruled out.</li> </ul> </li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
ElELYso (taliglucerase alfa)	200U/Vial Pws for Inj	02425637	DNP	E (SF)	PFI
Criteria	<ul style="list-style-type: none"> <li>○ Platelet count &lt;50 x 10<sup>9</sup>/L on two separate occasions at least one month apart. Higher cut offs may be considered in the event the patient is symptomatic with bleeding or bruising.</li> <li>○ At least two episodes of severely symptomatic splenic infarcts confirmed by CT or other imaging of the abdomen.</li> <li>● <b>Skeletal complications</b> <ul style="list-style-type: none"> <li>○ A single acute bone crisis severe enough to require hospitalization or marked incapacitation.</li> <li>○ Radiographic or MRI evidence of incipient destruction of any major joint (e.g., hips and shoulders) or significant worsening of bony pathology (e.g. marrow infiltration, avascular necrosis, and infarcts).</li> <li>○ Spontaneous fractures with evidence from imaging studies that recurrence is likely.</li> <li>○ Chronic bone pain causing significant loss of time from work or school and not controlled by administration of non-narcotic analgesics or anti-inflammatory drugs.</li> <li>○ Note: Patients who are scheduled for major joint replacement surgery, made necessary by skeletal complications of GD1, should be treated with enzyme therapy at a dosage of at least 30 units/kg every 2 weeks for at least 6 months before the joint replacement surgery and the dose continued until rehabilitation from the surgery is complete.</li> </ul> </li> <li>● <b>Gastrointestinal complications</b> <ul style="list-style-type: none"> <li>○ Evidence of significant liver dysfunction attributable to GD1, such as portal hypertension or impaired hepatic synthetic function. Elevation of transaminase levels with no evidence of portal hypertension or impairment in synthetic function is not an indication for ERT.</li> <li>○ Significant discomfort due to enlargement of the spleen or liver.</li> </ul> </li> <li>● <b>Pulmonary complications</b> <ul style="list-style-type: none"> <li>○ Evidence of clinically significant and/or progressive pulmonary disease due to GD1.</li> </ul> </li> <li>● <b>Systemic complications</b> <ul style="list-style-type: none"> <li>○ Growth failure in children: significant decrease in percentile linear growth over a 3 - 6 month period.</li> </ul> </li> </ul> <p><b>Exclusion Criteria</b></p> <ul style="list-style-type: none"> <li>● Due to the absence of data demonstrating therapy of asymptomatic patients alters long term outcomes, asymptomatic patients will not be considered for coverage.</li> <li>● Data does not suggest that ERT is effective in improving central nervous system involvement in patients with Type 2 and 3 disease. Therefore, patients exhibiting primary neurological disease due to GD1 will not be considered for coverage. Treatment for</li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR																										
<b>ElELYso</b> (taliglucerase alfa)	200U/Vial Pws for Inj	02425637	DNP	E (SF)	PFI																										
Criteria	<p>patients at risk of neuropathic disease should be guided by the non-neurological manifestations of their disease as outlined above and ERT should not be initiated in asymptomatic patients who have a genotype that increases their risk of neuropathic involvement.</p> <p><b>Continued Coverage</b></p> <ul style="list-style-type: none"> <li>• Patients' disease severity must be re-assessed annually.</li> <li>• A patient may receive approval for further coverage for treatment where there is demonstrated clinical improvement based on the expected response outlined below:</li> </ul> <table border="1"> <thead> <tr> <th>Indication for therapy</th> <th>Expected Response</th> </tr> </thead> <tbody> <tr> <td>Hemoglobin &lt; 85% of lower limit of age and sex-appropriate normal</td> <td>Increase hemoglobin levels to &gt; 110 for women and children and &gt; 120 for men</td> </tr> <tr> <td rowspan="3">Platelet count &lt; 50 x 10<sup>9</sup>/L on two separate occasions, or bleeding complications associated with thrombocytopenia irrespective of the platelet count.</td> <td>Increase platelet count to level sufficient to prevent spontaneous bleeding</td> </tr> <tr> <td>Normalization of platelet count in splenectomized patients</td> </tr> <tr> <td>In patients with intact spleen, an increase of at least 1.5X baseline value</td> </tr> <tr> <td rowspan="2">Two episodes of severely symptomatic splenic infarcts</td> <td>Reduction of spleen volume by 50%</td> </tr> <tr> <td>Prevention of further splenic infarcts</td> </tr> <tr> <td>Acute bone crises</td> <td>Prevent bone crises</td> </tr> <tr> <td>Radiographic or MRI evidence of incipient destruction of any major joint</td> <td>Improvement in imaging parameters (either MRI, QCSI<sup>1</sup>, or BMD)</td> </tr> <tr> <td>Spontaneous fractures</td> <td>Prevention of further fractures</td> </tr> <tr> <td>Chronic bone pain</td> <td>Reduce bone pain</td> </tr> <tr> <td>Major joint replacement surgery</td> <td>Optimize surgical outcome</td> </tr> <tr> <td>Significant hepatic dysfunction</td> <td>Improvement in hepatic function</td> </tr> <tr> <td rowspan="2">Symptomatic hepatosplenomegaly</td> <td>Reduction of spleen volume by 50%</td> </tr> <tr> <td>Reduction in liver volume by 30%</td> </tr> </tbody> </table>					Indication for therapy	Expected Response	Hemoglobin < 85% of lower limit of age and sex-appropriate normal	Increase hemoglobin levels to > 110 for women and children and > 120 for men	Platelet count < 50 x 10 <sup>9</sup> /L on two separate occasions, or bleeding complications associated with thrombocytopenia irrespective of the platelet count.	Increase platelet count to level sufficient to prevent spontaneous bleeding	Normalization of platelet count in splenectomized patients	In patients with intact spleen, an increase of at least 1.5X baseline value	Two episodes of severely symptomatic splenic infarcts	Reduction of spleen volume by 50%	Prevention of further splenic infarcts	Acute bone crises	Prevent bone crises	Radiographic or MRI evidence of incipient destruction of any major joint	Improvement in imaging parameters (either MRI, QCSI <sup>1</sup> , or BMD)	Spontaneous fractures	Prevention of further fractures	Chronic bone pain	Reduce bone pain	Major joint replacement surgery	Optimize surgical outcome	Significant hepatic dysfunction	Improvement in hepatic function	Symptomatic hepatosplenomegaly	Reduction of spleen volume by 50%	Reduction in liver volume by 30%
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New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>ElELYso</b> (taliglucerase alfa)	200U/Vial Pws for Inj	02425637	DNP	E (SF)	PFI
Criteria	<b>Indication for therapy</b>		<b>Expected Response</b>		
	Progressive pulmonary disease due to GD1		Improvement in pulmonary hypertension <sup>2</sup>		
			Improvement in oxygenation		
			Reversal of hepatopulmonary syndrome		
	Growth failure in children		Return to normal range of growth parameters		
	<sup>1.</sup> QCSI- quantitative chemical shift imaging <sup>2.</sup> May require adjuvant treatment for pulmonary hypertension  <b>Discontinuation of Coverage</b> <ul style="list-style-type: none"> <li>• Renewals will NOT be approved if: <ul style="list-style-type: none"> <li>○ The patient or the patient's specialist fails to comply adequately with treatment or measures taken to evaluate the effectiveness of the therapy (e.g. monitoring for expected response).</li> <li>○ Therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for treatment.</li> </ul> </li> </ul> <b>Claim Notes:</b> <ul style="list-style-type: none"> <li>• Approvals will be for a maximum of 60 units/kg every 2 weeks.</li> <li>• Initial Approval: 6 months.</li> <li>• Renewal Approval: 1 year.</li> <li>• Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs: <ul style="list-style-type: none"> <li>○ 00904383</li> <li>○ 00904385</li> </ul> </li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Mavenclad</b> (cladribine)	10mg Tab	02470179	DNP	E (SF)	EMD
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all the following criteria: <ul style="list-style-type: none"> <li>○ Confirmed diagnosis based on McDonald criteria.</li> <li>○ Has experienced one or more disabling relapses or new MRI activity in the past year.</li> </ul> </li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Mavenclad (cladribine)</b>	10mg Tab	02470179	DNP	E (SF)	EMD
Criteria	<ul style="list-style-type: none"> <li>○ Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5).</li> <li>○ Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab).</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.</li> <li>• A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>• Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis.</li> <li>• Approvals will be for 1.75mg/kg to a maximum of 200mg per treatment year.</li> <li>• Approval period: 2 years.</li> <li>• Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs:               <ul style="list-style-type: none"> <li>○ 00904524</li> <li>○ 00904525</li> <li>○ 00904526</li> </ul> </li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Mictoryl (propiverine hydrochloride)</b>	5mg Tab	02460289	DNP	E (F)	DUI
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of overactive bladder with symptoms of urgency incontinence and/or urinary frequency and urgency in pediatric patients under 18 years of age.</li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
VPRIV (velaglycerase alfa)	400U/Vial Pws for Inj	02357119	DNP	E (SF)	SHI
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with symptomatic Gaucher disease type 1 (GD1) for whom treatment with velaglycerase alfa is tolerated or not contraindicated.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Velaglycerase alfa is the preferred reimbursed enzyme replacement therapy (i.e. first tier) for all new and existing GD1.</li> <li>Requests for patients currently using taliglycerase alfa who do not have a contraindication or intolerance to velaglycerase alfa will be switched to velaglycerase alfa only.</li> <li>Requests for coverage must meet the criteria for diagnosis of GD1, indication for therapy and expected response to enzyme replacement therapy outlined below:</li> </ul> <p><b>Initial Coverage</b></p> <p><b>Diagnosis</b></p> <ul style="list-style-type: none"> <li>The diagnosis of GD1 must have been established by the demonstration of specific deficiency of glucocerebrosidase (GCase) in tissue or cultured skin fibroblasts, or by demonstration of the presence, in tissue or peripheral blood leukocytes, of mutations in the GCase gene known to result in severe enzyme deficiency.</li> <li>Other potentially confounding diagnoses, such as Hodgkin disease or other storage disorders, must have been ruled out. The symptoms experienced by the patient should be shown to be attributable to GD1 and not another condition that might mimic it.</li> <li>The patient should not have any GD1-related or other medical condition that might reasonably be expected to compromise their response to treatment. In some patients with GD1, secondary pathologic changes, such as avascular necrosis of bone, may already have occurred that would not be expected to respond to enzyme replacement. In such patients, reversal of the pathology is unlikely.</li> </ul> <p><b>Disease Severity</b></p> <p>Evidence of disease severity must be provided, and include at least one of the following:</p> <ul style="list-style-type: none"> <li><b>Hematological complications</b> <ul style="list-style-type: none"> <li>Hemoglobin &lt;85% of lower limit of age- and sex-appropriate normal after other causes of anemia, such as iron deficiency, have been treated or ruled out.</li> <li>Platelet count &lt;50 x 10<sup>9</sup>/L on two separate occasions at least one month apart. Higher cut offs may be considered in the event the patient is symptomatic with bleeding or bruising.</li> <li>At least two episodes of severely symptomatic splenic infarcts confirmed by CT or other imaging of the abdomen.</li> </ul> </li> <li><b>Skeletal complications</b> <ul style="list-style-type: none"> <li>A single acute bone crisis severe enough to require hospitalization or marked incapacitation.</li> </ul> </li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
VPRIV (velaglucerase alfa)	400U/Vial Pws for Inj	02357119	DNP	E (SF)	SHI
Criteria	<ul style="list-style-type: none"> <li>○ Radiographic or MRI evidence of incipient destruction of any major joint (e.g., hips and shoulders) or significant worsening of bony pathology (e.g. marrow infiltration, avascular necrosis, and infarcts).</li> <li>○ Spontaneous fractures with evidence from imaging studies that recurrence is likely.</li> <li>○ Chronic bone pain causing significant loss of time from work or school and not controlled by administration of non-narcotic analgesics or anti-inflammatory drugs.</li> <li>○ Note: Patients who are scheduled for major joint replacement surgery, made necessary by skeletal complications of GD1, should be treated with enzyme therapy at a dosage of at least 30 units/kg every 2 weeks for at least 6 months before the joint replacement surgery and the dose continued until rehabilitation from the surgery is complete.</li> </ul> <ul style="list-style-type: none"> <li>● <b>Gastrointestinal complications</b> <ul style="list-style-type: none"> <li>○ Evidence of significant liver dysfunction attributable to GD1, such as portal hypertension or impaired hepatic synthetic function. Elevation of transaminase levels with no evidence of portal hypertension or impairment in synthetic function is not an indication for ERT.</li> <li>○ Significant discomfort due to enlargement of the spleen or liver.</li> </ul> </li> <li>● <b>Pulmonary complications</b> <ul style="list-style-type: none"> <li>○ Evidence of clinically significant and/or progressive pulmonary disease due to GD1.</li> </ul> </li> <li>● <b>Systemic complications</b> <ul style="list-style-type: none"> <li>○ Growth failure in children: significant decrease in percentile linear growth over a 3 - 6 month period.</li> </ul> </li> </ul> <p><b>Exclusion Criteria</b></p> <ul style="list-style-type: none"> <li>● Due to the absence of data demonstrating therapy of asymptomatic patients alters long term outcomes, asymptomatic patients will not be considered for coverage.</li> <li>● Data does not suggest that ERT is effective in improving central nervous system involvement in patients with Type 2 and 3 disease. Therefore, patients exhibiting primary neurological disease due to GD1 will not be considered for coverage. Treatment for patients at risk of neuronopathic disease should be guided by the non-neurological manifestations of their disease as outlined above and ERT should not be initiated in asymptomatic patients who have a genotype that increases their risk of neuronopathic involvement.</li> </ul> <p><b>Continued Coverage</b></p> <ul style="list-style-type: none"> <li>● Patients' disease severity must be re-assessed annually.           <ul style="list-style-type: none"> <li>○ A patient may receive approval for further coverage for treatment where there is demonstrated clinical improvement based on the expected response outlined below:</li> </ul> </li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
VPRIV (velaglucerase alfa)	400U/Vial Pws for Inj	02357119	DNP	E (SF)	SHI
Criteria	<b>Indication for therapy</b>		<b>Expected Response</b>		
	Hemoglobin < 85% of lower limit of age and sex-appropriate normal		Increase hemoglobin levels to > 110 for women and children and > 120 for men		
	Platelet count < 50 x 10 <sup>9</sup> /L on two separate occasions, or bleeding complications associated with thrombocytopenia irrespective of the platelet count.		Increase platelet count to level sufficient to prevent spontaneous bleeding		
			Normalization of platelet count in splenectomized patients		
			In patients with intact spleen, an increase of at least 1.5X baseline value		
	Two episodes of severely symptomatic splenic infarcts		Reduction of spleen volume by 50%		
			Prevention of further splenic infarcts		
	Acute bone crises		Prevent bone crises		
	Radiographic or MRI evidence of incipient destruction of any major joint		Improvement in imaging parameters (either MRI, QCSI <sup>1</sup> , or BMD)		
	Spontaneous fractures		Prevention of further fractures		
	Chronic bone pain		Reduce bone pain		
	Major joint replacement surgery		Optimize surgical outcome		
	Significant hepatic dysfunction		Improvement in hepatic function		
	Symptomatic hepatosplenomegaly		Reduction of spleen volume by 50%		
			Reduction in liver volume by 30%		
	Progressive pulmonary disease due to GD1		Improvement in pulmonary hypertension <sup>2</sup>		
			Improvement in oxygenation		
			Reversal of hepatopulmonary syndrome		
	Growth failure in children		Return to normal range of growth parameters		
	<sup>1.</sup> QCSI- quantitative chemical shift imaging <sup>2.</sup> May require adjuvant treatment for pulmonary hypertension				
	<b>Discontinuation of Coverage</b> <ul style="list-style-type: none"> <li>• Renewals will NOT be approved if:             <ul style="list-style-type: none"> <li>○ The patient or the patient's specialist fails to comply adequately with treatment or measures taken to evaluate the effectiveness of the therapy (e.g. monitoring for expected response).</li> <li>○ Therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for treatment.</li> </ul> </li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
VPRIV (velaglucerase alfa)	400U/Vial Pws for Inj	02357119	DNP	E (SF)	SHI
Criteria	<p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>• Approvals will be for a maximum of 60 units/kg every 2 weeks.</li> <li>• Initial Approval: 6 months.</li> <li>• Renewal Approval: 1 year.</li> <li>• Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PINs: <ul style="list-style-type: none"> <li>○ 00904378</li> <li>○ 00904379</li> <li>○ 00904380</li> </ul> </li> </ul>				

### Criteria Updates

The following criteria has been updated effective **immediately**:

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Lenvima (lenvatinib)	4mg Compliance Pack	02484056	DNP	E (SFC)	EIS
	8mg Compliance Pack	02468220	DNP	E (SFC)	EIS
	12mg Compliance Pack	02484129	DNP	E (SFC)	EIS
Criteria	<ul style="list-style-type: none"> <li>• For the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma who meet all the following criteria: <ul style="list-style-type: none"> <li>○ Child-Pugh class status of A.</li> <li>○ ECOG performance status of 0 or 1.</li> <li>○ Less than 50% liver involvement and no invasion of the bile duct or main portal vein.</li> <li>○ No brain metastases or prior liver transplantation.</li> </ul> </li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• Treatment should be continued until disease progression or unacceptable toxicity.</li> <li>• Patients who are unable to tolerate lenvatinib may be switched to sorafenib if there is no disease progression and provided all other funding criteria are met.</li> <li>• Patients with disease progression on lenvatinib are not eligible for reimbursement of sorafenib.</li> </ul>				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Nexavar (Sorafenib)</b>	200mg Tab	02284227	DNP	E (SFC)	BAY
Criteria	<ul style="list-style-type: none"> <li>As a single agent first line systemic therapy option in adult patients with a diagnosis of hepatocellular carcinoma (HCC) with Child-Pugh Class A liver dysfunction (mild hepatic impairment) with ECOG performance status 0-1; and who have either progression of disease, or who are not candidates for curative intent treatments (transplantation, hepatic resection), or other well established palliative interventions (ablation, transcatheter arterial chemo-embolization (TACE), internal radiation).</li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>Patients who are unable to tolerate sorafenib may be switched to lenvatinib if there is no disease progression and provided all other funding criteria are met.</li> <li>Patients with disease progression on sorafenib are not eligible for reimbursement of lenvatinib.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Stivarga (Regorafenib)</b>	40mg Tab	02403390	DNP	E (SFC)	BAY
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have experienced disease progression on sorafenib or lenvatinib and meet all of the following criteria: <ul style="list-style-type: none"> <li>Child-Pugh class status of A.</li> <li>ECOG performance status of 0 or 1.</li> </ul> </li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>Treatment should continue until disease progression or unacceptable toxicity.</li> <li>Patients with disease progression on sorafenib must have tolerated a minimum dose of 400 mg per day for at least 20 of the last 28 days of treatment.</li> </ul>				

## New Products

Effective **immediately**, the following new products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Nucala	100mg/mL Autoinjector	02492989	DNP	E (SF)	GSK
Nucala	100mg/mL Pre-filled Syringe	02492997	DNP	E (SF)	GSK
Vyzulta	0.024% Oph Sol	02484218	DNP	E (SF)	BSL



## Temporary Addition of New Benefits

Under the interim order in relation to COVID-19, Health Canada is allowing certain drugs that may not fully meet regulatory requirements to be imported and sold in Canada. Drugs that are eligible under the interim order are included on the List of Drugs for Exceptional Importation and Sale and are called “designated drugs.”

Pharmacists are advised that there may be differences between the approved “designated drug” and their Canadian Reference Product. Health Canada information specific to each product is available on the List of Drugs for Exceptional Importation and Sale. Pharmacists are directed to consult and use this information when prescribing or dispensing these products.

The Interim Order and the List of Drugs for Exceptional Importation and Sale can be found at the following links:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods.html>

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/list.html>

The Nova Scotia Pharmacare Programs are adding the following products as temporary new benefits effective **immediately**:

PRODUCT	STRENGTH	PIN	PRESCRIBER	BENEFIT STATUS	MFR
PTU	50mg	09858122	DNP	SFC	PCI
Timo-Stulln Drops	0.5% Oph Sol	09858120	DNP	SFC	PST

## New Form

New request form for Ocrevus can be found at the following link:

<https://novascotia.ca/dhw/pharmacare/exception-status-drugs.asp>

# PharmacareNEWS

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### Nova Scotia Formulary Updates

#### New Exception Status Benefits

- Hemangiol (propranolol)
- Strensiq (asfotase alfa)

#### Criteria Updates

- Botox (Onabotulinumtoxin A)

#### Changes to Insured Oral Compounded Solutions

#### Correction

## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Hemangiol</b> <b>(propranolol)</b>	3.75mg/mL Sol	02457857	DNP	E (F)	PFB
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of patients with proliferating infantile hemangioma that is:                             <ul style="list-style-type: none"> <li>○ Life-or function-threatening OR</li> <li>○ Ulcerated with pain or not responding to simple wound care measures OR</li> <li>○ At risk of permanent scarring or disfigurement</li> </ul> </li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Strensiq</b> <b>(asfotase alfa)</b>	18mg/0.45 mL Single Use Vial	02444615	DNP	E (F)	ALX
	28mg /0.7mL Single Use Vial	02444623	DNP	E (F)	ALX
	40mg/1mL Single Use Vial	02444631	DNP	E (F)	ALX
	80mg/0.8mL Single Use Vial	02444658	DNP	E (F)	ALX
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of patients with perinatal, infantile, or juvenile-onset hypophosphatasia (HPP).</li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Strensiq (asfotase alfa)</b>	18mg/0.45 mL Single Use Vial	02444615	DNP	E (F)	ALX
	28mg /0.7mL Single Use Vial	02444623	DNP	E (F)	ALX
	40mg/1mL Single Use Vial	02444631	DNP	E (F)	ALX
	80mg/0.8mL Single Use Vial	02444658	DNP	E (F)	ALX
Criteria	<p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>Eligibility for the treatment of HPP is determined by the Canadian HPP Clinical Expert Committee. Please contact the Nova Scotia Pharmacare Programs via fax at 1-888-594-4440 for the request form.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Must be prescribed by a metabolic specialist with expertise in the diagnosis and management of HPP.</li> <li>Claims for Strensiq 18mg/0.45mL, 28mg/0.7mL, 40mg/1mL and 80mg/0.8mL Single Use Vials that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions. Please refer to Appendix III of the Nova Scotia Formulary for additional PINs.</li> </ul>				

## Criteria Update

The following indication has been added to existing criteria **effective immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Botox (Onabotulinumt- oxin A)</b>	50U/Vial	00999443	DNP	E (SF)	ALL
	100U/Vial	01981501	DNP	E (SF)	ALL
Criteria	<ul style="list-style-type: none"> <li>For the treatment of overactive bladder (OAB) with symptoms of urgency, urgency incontinence, and urinary frequency, in adult patients who have an intolerance or insufficient response to an adequate trial of at least two other pharmacologic treatments (e.g. anticholinergics, mirabegron).</li> </ul> <p><b>Renewal criteria:</b></p> <ul style="list-style-type: none"> <li>Requests for renewal should provide objective evidence of a treatment response, defined as a reduction of at least 50% in the frequency of urinary incontinence episodes.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Must be prescribed and administered by a urologist.</li> <li>Initial approval period: 12 weeks (one dose).</li> <li>Renewal approval period: Maximum of 3 doses per year in responders, at a frequency of no more than once every twelve weeks.</li> </ul>				

## Changes to Insured Oral Compounded Solutions

**Effective September 1st, 2020**, all oral compounds listed on the Nova Scotia Formulary for children 12 years and under will now be benefits for individuals 19 years and younger if they clinically require this specialized format. Also, a number of oral compounds were added to the existing list of oral compounds under the Nova Scotia Pharmacare programs. The specific products can be found in the next update of the Nova Scotia Formulary.

The following oral compounds have moved to non-benefit status and will no longer be covered under the Nova Scotia Pharmacare Programs.

- Clotrimazole Oral Suspension
- Labetalol Oral Suspension
- Naproxen Oral Suspension

## Correction

Please be advised that there was an error made in the July 2020 Pharmacist's Bulletin concerning the benefit status of the following products. We apologize for any inconvenience.

### New Products

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	CORRECT BENEFIT STATUS	MFR
Vyzulta	0.024% Oph Sol	02484218	DNP	E (SF)	SF	BSL

### Temporary Addition of New Benefits

PRODUCT	STRENGTH	PIN	PRESCRIBER	BENEFIT STATUS	CORRECT BENEFIT STATUS	MFR
PTU	50mg	09858122	DNP	SFC	SF	PCI
Timo-Stulln Drops	0.5% Oph Sol	09858120	DNP	SFC	SF	PST



# PharmacareNEWS

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### **Nova Scotia Formulary Updates**

Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2020-2021 Influenza Season

## **Nova Scotia Formulary Updates**

### **Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2020-2021 Influenza Season**

#### **Who is eligible to have publicly-funded influenza vaccine administered by a pharmacist?**

All individuals 2 years of age and over can have publicly-funded influenza vaccine administered by a pharmacist. As the publicly-funded influenza vaccine is available free of charge, no individual is to be charged for the vaccine.

The expanded age range of 2 years of age and over reflects the April 2020 amendment to the NSCP Standards of Practice for Drug Administration.

Pharmacists must ensure they are competent to administer the influenza vaccine in this younger age group in terms of technique, needle size, site of injection etc. One example of a resource is: <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information/page-8-vaccine-administration-practices.html>

Please be advised that **Afluria Tetra** is a new product that will be used this year and is **indicated for patients 5 years of age and older**. Pharmacies will need to be careful to screen for the age of the patient and those age 2-4 should not be provided this product. New PINS have been created for this product and can be found on page 4.

#### **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 DHW. There are no copayments or deductibles associated with the administration of the influenza vaccine for residents with a valid Nova Scotia Health Card Number. All other individuals are responsible for paying any 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 2020-2021 influenza season.

**Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2020-2021 Influenza Season Continued...**

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* which can be found at the following link: [https://www.nspharmacists.ca/wp-content/uploads/2019/10/SOP\\_DrugAdministration.pdf](https://www.nspharmacists.ca/wp-content/uploads/2019/10/SOP_DrugAdministration.pdf)
2. Sign the *Confirmation of Agreement Form* certifying agreement with the Pharmacy Service Agreement (Appendix III) 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. Pharmacies setting up a pharmacy to provide publicly funded vaccines must contact their public health office. Public health requires additional information prior to setting up a pharmacy as a provider in Panorama. Public health also requires a 7 day temperature log with temperatures documented two times per day to set up a provider to receive publicly funded vaccine.

**Where do pharmacies get publicly-funded influenza vaccine?**

All publicly-funded influenza vaccine must be obtained from the local public health office. The supply and distribution of Fluzone High-Dose will be coordinated by the Provincial Bio-Depot and only pharmacists designated to provide Fluzone HD to residents 65 years of age and older at a LTCF will receive Fluzone HD.

All providers are responsible for any transportation costs to obtain publicly-funded vaccine. Pharmacy orders can be delivered by Med-Express in Central Zone. The Pharmacy must have an account with Med-Express. Pharmacies should contact their local public health office to place their order for vaccine and to arrange pick-up. For flu season 2020-21 during Covid pharmacies will be contacted to book an appointment to pick-up their publicly funded flu vaccine. This is to minimize crowds and possible risk of spreading Covid. Please review the Immunization Toolkit (located at <http://www.cdha.nshealth.ca/immunization-forms>) for information on transporting biologicals to ensure you have all the required equipment when you pick up your vaccine. (e.g. a hard sided cooler which seals properly, ice pack and an insulating layer to ensure the ice does not lay on the vaccine product). Public health can only release vaccine in accordance with this protocol.

**When can pharmacists begin administering publicly-funded influenza vaccine?**

Pharmacists may begin administering publicly-funded influenza vaccine as soon as they receive it.

**How do pharmacies bill DHW for influenza vaccine administration fees?**

***To ensure claims are adjudicated correctly, all influenza claims must be adjudicated using a quantity of 1, as well as the correct DIN and/or PIN.***

Fees for the administration of publicly-funded influenza vaccine to Nova Scotia residents with a valid Nova Scotia Health Card must be billed to DHW 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.



**Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2020-2021 Influenza Season Continued...**

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.

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 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.** For information of what adverse events to report please review "It's the Law: Reporting Notifiable Diseases and Conditions" (located at <https://novascotia.ca/dhw/CDPC/info-for-professionals.asp>).

Providers should document an AEFI using the Public Health Agency of Canada AEFI form (located at <https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and **forward the form to the local public health office.** The local public health office reviews these reports and facilitates with Department of Health and Wellness the reporting of AEFIs 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 they can be used.**

**Claim Submissions for Publicly-Funded Influenza Vaccine by Pharmacist**

Fees for the administration of publicly-funded influenza vaccines are for the service of administering the influenza vaccine, not the amount of vaccine administered. Therefore, all influenza claims **must be** adjudicated using a **quantity of 1**, as well as the correct DIN and/or PIN. Claims must not be adjudicated using a quantity <1.

Reports will be generated by Nova Scotia Pharmacare to identify claims adjudicated with an improper quantity (<1) and incorrect PINS (e.g. PIN for pregnant women, used to adjudicate a claim for a male). Pharmacies will be contacted regarding incorrect claims. These claims must be reversed by the pharmacy and resubmitted correctly. Any claims that have been identified on these reports, which are not corrected, may be subject to audit and possible recovery of administration fees.



Administration of Publicly-Funded Influenza Vaccine by Pharmacists for the 2020-2021 Influenza Season Continued...

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

CPHA CLAIM STANDARD FIELD #	CPHA CLAIM STANDARD FIELD NAME	CONTENT
D.56.03	DIN/GP#/PIN	<p><b>DINs</b></p> <ul style="list-style-type: none"> <li>- Fluzone Quadrivalent MDV 02432730</li> <li>- Fluzone Quadrivalent PFS 02420643</li> <li>- FluLaval Tetra 02420783</li> <li>- Fluzone High-Dose 02445646*</li> </ul> <p>* Only for residents of Long Term Care Facilities (nursing homes and residential care facilities) ≥65 years of age</p> <ul style="list-style-type: none"> <li>- Afluria Tetra Quadrivalent MDV 02473313**</li> <li>- Afluria Tetra Quadrivalent PFS 02473283**</li> </ul> <p>** Age indication of 5 years of age or older</p> <p><b>PIN for pregnant women</b></p> <ul style="list-style-type: none"> <li>- Fluzone Quadrivalent 93899895</li> <li>- FluLaval Tetra 93899893</li> <li>- Afluria Tetra Quadrivalent 96599953</li> </ul> <p><b>PIN for second dose for children</b></p> <ul style="list-style-type: none"> <li>- Fluzone Quadrivalent 93899896</li> <li>- FluLaval Tetra 93899894</li> <li>- Afluria Tetra Quadrivalent 96599952*</li> </ul> <p>*Age indication of 5 years of age or older</p>
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	Pharmacists prescriber ID
D.66.03	Drug Cost/Product Value	DDDDD (dollar value - not adjudicated)
D.67.03	Cost Upcharge	DDDDD (dollar value- not adjudicated)
D.68.03	Professional Fee	\$12.40 until March 31, 2021 \$12.55 effective April 1, 2021

# PharmacareNEWS

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### Nova Scotia Formulary Updates

#### New Exception Status Benefits

- Ozempic (semaglutide)
- Humira (adalimumab)
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#### Criteria Updates

- Ibrance (palbociclib)
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#### New Benefit – US-Labelled Sublocade

## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Ozempic (semaglutide)</b>	2mg/1.5mL Pre-Filled Pen	02471477	DNP	E (SF)	NNO
	4mg/3mL Pre-Filled Pen	02471469	DNP	E (SF)	NNO
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Humira (adalimumab)</b>	20mg/0.2mL Pre-Filled Syringe	02474263	DNP	E (SF)	ABV
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of polyarticular juvenile idiopathic arthritis (pJIA) with the following criteria:                             <ul style="list-style-type: none"> <li>○ For patients aged 4-17 years with moderate or severe pJIA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs); and</li> <li>○ Treatment must be initiated by a rheumatologist who is familiar with the use of DMARDs and/or biologic DMARDs in children.</li> </ul> </li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Riximyo (rituximab)</b>	10mg/mL Vial	02498316	DNP	E (SF)	SDZ
Criteria	<ul style="list-style-type: none"> <li>For the treatment of adult patients with severe active rheumatoid arthritis who have failed to respond to an adequate trial with an anti-TNF agent.</li> <li>Cannot be used concomitantly with anti-TNF agents.</li> <li>Written request from a rheumatologist or prescriber with a specialty in rheumatology.</li> <li>Approval for re-treatment with rituximab will only be considered for patients who have achieved a response, followed by a subsequent loss of effect and, after an interval of no less than six months from the previous dose.</li> </ul> <p><b>For rituximab-naïve patients whose rituximab therapy is initiated after November 1, 2020, a rituximab biosimilar will be the product approved.</b></p>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Ruxience (rituximab)</b>	10mg/mL Vial	02495724	DNP	E (SF)	PFI
Criteria	<ul style="list-style-type: none"> <li>For the treatment of adult patients with severe active rheumatoid arthritis who have failed to respond to an adequate trial with an anti-TNF agent.</li> <li>Cannot be used concomitantly with anti-TNF agents.</li> <li>Written request from a rheumatologist or prescriber with a specialty in rheumatology.</li> <li>Approval for re-treatment with rituximab will only be considered for patients who have achieved a response, followed by a subsequent loss of effect and, after an interval of no less than six months from the previous dose.</li> <li>For the induction of remission in patients with severely active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) who have severe intolerance or other contraindication to cyclophosphamide, or who have failed an adequate trial of cyclophosphamide</li> </ul> <p><b>For rituximab-naïve patients whose rituximab therapy is initiated after November 1, 2020, a rituximab biosimilar will be the product approved.</b></p>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Velphoro</b> (sucroferric oxyhydroxide)	500mg Tab	02471574	DNP	E (SF)	OTS
Criteria	<ul style="list-style-type: none"> <li>For the treatment of hyperphosphatemia (&gt;1.8 mmol/L) in patients with end-stage renal disease (eGFR &lt; 15 mL/min) who have: <ul style="list-style-type: none"> <li>Inadequate control of phosphate levels on a calcium based phosphate binder, OR</li> <li>Hypercalcemia (corrected for albumin), OR</li> <li>Calciphylaxis (calcific arteriopathy)</li> </ul> </li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Must be prescribed by a nephrologist or other prescriber within the Provincial Dialysis Program.</li> <li>Initial Approval: 6 months.</li> <li>Renewal Approval: 1 year. Confirmation of improvement of phosphate levels is required (lab values must be provided).</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Vyvanse</b> (lisdexamfetamine dimesylate)	10mg Chewtab	02490226	DNP	E (SF)	TAK
	20mg Chewtab	02490234	DNP	E (SF)	TAK
	30mg Chewtab	02490242	DNP	E (SF)	TAK
	40mg Chewtab	02490250	DNP	E (SF)	TAK
	50mg Chewtab	02490269	DNP	E (SF)	TAK
	60mg Chewtab	02490277	DNP	E (SF)	TAK
Criteria	<ul style="list-style-type: none"> <li>For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients who: <ul style="list-style-type: none"> <li>demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning; and</li> <li>have been tried on methylphenidate (immediate release or long-acting formulation) or dexamphetamine with unsatisfactory results.</li> </ul> </li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>Requests will be considered from prescribers with expertise in ADHD.</li> <li>The maximum dose reimbursed is 60mg daily.</li> </ul>				

## Criteria Updates

The following criteria has been added to existing criteria **effective immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Ibrance</b> <b>(palbociclib)</b>	75mg Cap	02453150	DNP	E (SFC)	PFI
	100mg Cap	02453169	DNP	E (SFC)	PFI
	125mg Cap	02453177	DNP	E (SFC)	PFI
	75 mg Tab	02493535	DNP	E (SFC)	PFI
	100mg Tab	02493543	DNP	E (SFC)	PFI
	125mg Tab	02493551	DNP	E (SFC)	PFI
Criteria	<ul style="list-style-type: none"> <li>In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER 2 negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression. Patients may have also received up to one prior line of chemotherapy for advanced disease. Patients should have a good performance status, without active or uncontrolled metastases to the central nervous system and can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist).</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Treatment should continue until unacceptable toxicity or disease progression.</li> <li>Patients who progress <math>\leq</math> 12 months from (neo)adjuvant therapy are eligible for treatment with palbociclib plus fulvestrant.</li> <li>Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with palbociclib with fulvestrant.</li> <li>Patients currently receiving fulvestrant monotherapy, and who have not progressed may have palbociclib added, provided they are CDK 4/6 inhibitor naïve and otherwise meet funding criteria.</li> <li>Patients who previously received everolimus plus exemestane will be eligible for funding of palbociclib plus fulvestrant on progression, provided that treatment was started prior to funding of CDK 4/6 + fulvestrant, patient must be CDK 4/6 naïve and otherwise meet funding criteria.</li> </ul>				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kisqali (ribociclib)	200mg Tab	02473569	DNP	E (SFC)	NVR
Criteria	<ul style="list-style-type: none"> <li>In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER 2 negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression. Patients may have also received up to one prior line of chemotherapy for advanced disease. Patients should have a good performance status, without active or uncontrolled metastases to the central nervous system and can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist).</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Treatment should continue until unacceptable toxicity or disease progression.</li> <li>Patients who progress <math>\leq</math> 12 months from (neo) adjuvant therapy are eligible for treatment with ribociclib plus fulvestrant.</li> <li>Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with ribociclib with fulvestrant.</li> <li>Patients currently receiving fulvestrant monotherapy, and who have not progressed may have ribociclib added, provided they are CDK 4/6 inhibitor naïve and otherwise meet funding criteria.</li> <li>Patients who previously received everolimus plus exemestane will be eligible for funding of ribociclib plus fulvestrant on progression, provided that treatment was started prior to funding of CDK 4/6 + fulvestrant, patient must be CDK 4/6 naïve and otherwise meet funding criteria.</li> </ul>				

### Notification of Fibrystal Delisting

Allergan Inc., the company that manufactures Fibrystal in Canada has voluntarily withdrawn the product from the Canadian market, due to safety concerns.

For more information on the recall please see:

<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/74063a-eng.php>

Effective October 1st, 2020, Fibrystal has been delisted as a benefit under the Nova Scotia Pharmacare Programs.

PRODUCT	STRENGTH	DIN	MFR
Fibrystal	5mg Tab	02408163	ALL

## New Benefit – US-Labelled Sublocade

Indivior Canada Ltd. has received approval from Health Canada for the importation and release of a limited supply of US-labelled Sublocade to mitigate the shortages of Sublocade in Canada related to the COVID-19 pandemic.

The Nova Scotia Pharmacare Programs will be adding this product as a temporary benefit effective **immediately**.

The US-labelled Sublocade products are similar to the Canadian labelled Sublocade products and should be used as per the Canadian Product Monograph.

PRODUCT	STRENGTH	PIN	PRESCRIBER	BENEFIT STATUS	MFR
Sublocade	100 mg/0.5 mL Inj	09858127	DN	E (SF)	ICL
Sublocade	300mg/1.5 mL Inj	09858128	DN	E (SF)	ICL





# PharmacareNEWS

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## **Nova Scotia Formulary Updates**

### **Waiver of Audit Requirement for Prescriber Notification**

For prescription renewals and assessment and prescribing services that result in a prescription, in support of the Nova Scotia College of Pharmacist's standards for *Prescribing in a Public Health Emergency/Crisis*, the audit requirement for documentation of prescriber notification or that the prescribing information was provided to the patient is waived until further notice.

### **Virtual Care Update**

#### ***Virtual Delivery of Pharmacy Services Extended***

The waiver of the in-person requirement for delivery of publicly funded assessment and prescribing services has been extended to December 31, 2020. More information on new claim requirements for pharmacy services to support virtual care can be found below.

#### **Criteria Codes to be Required for All Pharmacy Service Claims Effective December 1, 2020**

To support monitoring and evaluation of virtual pharmacy services to inform development of a DHW policy on virtual care, all DHW-funded service claims will require criteria codes effective December 1, 2020. This includes prescription renewals, assessment and prescribing for contraception management, uncomplicated cystitis and herpes zoster, and medication reviews. The code ED must be entered in the Intervention Code field and one of the following codes must be entered in the Special Authorization Code field for all service claims:

- 91 = In-person
- 92 = Telephone
- 93 = Video

When video technology is used, the platform must be compliant with the privacy and security requirements of the *Personal Health Information Act* (PHIA).

Virtual Care Update Continued...

**Claims Submission Field Content for Adjudication with a Criteria Code-  
 Pharmacy Special Services for Virtual Care Data**

Field #	Field Name	Content
D.56.03	DIN/GP#/PIN	Pharmacy Services PIN
D.57.03	Special Service Code	002 (pharmacist intervention) or 003 (pharmacist consultation for Medication Review)
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	Licence number
D.64.03	Special Authorization Code	<b>91 (In Person), 92 (Telephone) or 93 (Video)</b>
D.65.03	Intervention Code	ED
D.66.03	Drug Cost/Product Value	DDDDD (dollar value – not adjudicated)
D.67.03	Cost Upcharge	DDDDD (dollar value – not adjudicated)
D.68.03	Professional Fee	DDDDD (dollar value – not adjudicated)
D.72.03	Special Services Fee(s)	Special Service Fee Associated with PIN

**Medication Reviews Approved for Virtual Care Delivery**

Advanced, Basic and Follow-up medication review services for eligible Pharmacare beneficiaries may be delivered by telephone or a PHIA-compliant video platform until December 31, 2020. Effective December 1, 2020, all claims for medication reviews must contain the appropriate criteria code for either in-person, telephone or video delivery. For virtual services, pharmacists must continue to provide patients with the comprehensive drug list that is dated and authorized with the pharmacist's signature and must obtain and document the patient's consent to the review. However, the patient's signature on the list will not be subject to audit for virtual services.

In addition to meeting all existing eligibility requirements as per the Pharmacy Guide, pharmacists may initiate a virtual Basic or Advanced Medication Review with a client only when the individual meets one of the following conditions, which must be documented in the patient file and available for audit:

- Recently discharged from hospital.
- No primary care provider for at least four to six months.
- Has a primary care provider but regularly brings in prescriptions from other prescribers (e.g. walk-in clinics or duty doctors).
- Recent change in medications, specifically tapering up or down or switching between medications.
- Taking new medications that have a high likelihood of side effects in the first few months of use that may lead to adherence or efficacy issues (e.g. antidepressants).
- Experiencing renal or hepatic function decline.
- Starting compliance-packed medications.

### Virtual Care Update Continued...

- Communicates that they think they are on too many medications or that they have financial concerns about their drug costs.
- Consistently early or late filling prescriptions.
- Appears to be confused about their medications.

### Coverage of Influenza Vaccines Administered by Pharmacy Technicians

In line with the amended *Pharmacy Practice Regulations* effective October 5, 2020, DHW will accept claims for seasonal influenza vaccine when the technical aspect of the administration has been delegated to a pharmacy technician, when performed in compliance with the regulations and standards of practice. Claims for such services should be billed as usual under the supervising pharmacist's prescriber ID at the maximum special service fee for Flu Vaccine Administration as per the *Pharmacy Service Agreement*.

### New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Kevzara</b> <b>(sarilumab)</b>	150mg/1.14mL Prefilled Pen	02472961	DNP	E (SF)	SAV
	200mg/1.14mL Prefilled Pen	02472988	DNP	E (SF)	SAV
	150mg/1.14mL Prefilled Syringe	02460521	DNP	E (SF)	SAV
	200mg/1.14mL Prefilled Syringe	02460548	DNP	E (SF)	SAV
Criteria	<ul style="list-style-type: none"> <li>• For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to: <ul style="list-style-type: none"> <li>○ methotrexate (oral or parenteral) at a dose of <math>\geq 20</math> mg weekly (<math>\geq 15</math>mg if patient is <math>\geq 65</math> years of age), OR</li> <li>○ use in combination with another DMARD, for a minimum of 12 weeks; AND</li> <li>○ methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.</li> </ul> </li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>• For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.</li> <li>• Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use.</li> <li>• If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.</li> <li>• Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.</li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Kezara</b> (sarilumab)	150mg/1.14mL Prefilled Pen	02472961	DNP	E (SF)	SAV
	200mg/1.14mL Prefilled Pen	02472988	DNP	E (SF)	SAV
	150mg/1.14mL Prefilled Syringe	02460521	DNP	E (SF)	SAV
	200mg/1.14mL Prefilled Syringe	02460548	DNP	E (SF)	SAV
Criteria	<ul style="list-style-type: none"> <li>Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Must be prescribed by a rheumatologist.</li> <li>Combined use of more than one biologic DMARD will not be reimbursed.</li> <li>Initial Approval: 6 months.</li> <li>Renewal Approval: 1 year. Confirmation of continued response is required.</li> </ul>				

### Criteria Updates

The following criteria has been updated **effective immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Ibrance</b> (palbociclib)	75mg Cap	02453150	DNP	E (SFC)	PFI
	100mg Cap	02453169	DNP	E (SFC)	PFI
	125mg Cap	02453177	DNP	E (SFC)	PFI
	75 mg Tab	02493535	DNP	E (SFC)	PFI
	100mg Tab	02493543	DNP	E (SFC)	PFI
	125mg Tab	02493551	DNP	E (SFC)	PFI
Criteria	<p><b>ER Positive, HER2-Negative Advanced Breast Cancer in Combination With an Aromatase Inhibitor (AI)</b></p> <ul style="list-style-type: none"> <li>In combination with an aromatase inhibitor (AI) (i.e. letrozole, anastrozole or exemestane) for the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER 2) negative advanced breast cancer who have not received any prior endocrine-based treatment for metastatic disease. Patients may have received up to one prior line of chemotherapy for advanced disease.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Treatment should continue until unacceptable toxicity or disease progression.</li> <li>Patients should have a good performance status and not be resistant to prior (neo) adjuvant aromatase inhibitor therapy (i.e. have the potential to benefit from first-line endocrine based therapy), without active or uncontrolled metastases to the central nervous system.</li> <li>Patients will be eligible for either palbociclib plus an aromatase inhibitor in the first line setting or everolimus plus exemestane as a subsequent line of therapy, but not both therapies.</li> </ul>				

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Ibrance</b> <b>(palbociclib)</b>	75mg Cap	02453150	DNP	E (SFC)	PFI
	100mg Cap	02453169	DNP	E (SFC)	PFI
	125mg Cap	02453177	DNP	E (SFC)	PFI
	75 mg Tab	02493535	DNP	E (SFC)	PFI
	100mg Tab	02493543	DNP	E (SFC)	PFI
	125mg Tab	02493551	DNP	E (SFC)	PFI

Criteria

Patients eligible include:

- Pre and peri-menopausal patients (should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist)
- Males
- Patients with bone-only metastases
- Patients who are HER2 equivocal by FISH testing (these patients are HER2 negative)
- Patients currently receiving first line aromatase inhibitor monotherapy for ER positive, HER2-negative metastatic breast cancer may have palbociclib added provided the above criteria is met.

**HR Positive, HER2-Negative Advanced or Metastatic Breast Cancer in Combination With Fulvestrant**

- In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER 2 negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. Patients may have also received up to one prior line of chemotherapy for advanced disease. Patients should have a good performance status, without active or uncontrolled metastases to the central nervous system and can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist).

**Clinical Notes:**

- Treatment should continue until unacceptable toxicity or disease progression.
- Patients who progress ≤ 12 months from (neo) adjuvant therapy are eligible for treatment with palbociclib plus fulvestrant.
- Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with palbociclib with fulvestrant.
- Patients currently receiving fulvestrant monotherapy, and who have not progressed may have palbociclib added, provided they are CDK 4/6 inhibitor naïve and otherwise meet funding criteria.
- Patients who previously received everolimus plus exemestane will be eligible for funding of palbociclib plus fulvestrant on progression, provided that treatment was started prior to funding of CDK 4/6 + fulvestrant, patient must be CDK 4/6 naïve and otherwise meet funding criteria.

Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Kisqali (ribociclib)	200mg Tab	02473569	DNP	E (SFC)	NVR
Criteria	<p><b>ER Positive, HER2-Negative Advanced Breast Cancer in Combination With an Aromatase Inhibitor (AI)</b></p> <ul style="list-style-type: none"> <li>In combination with an aromatase inhibitor (AI) (i.e. letrozole, anastrozole or exemestane) for the treatment of post-menopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER 2) negative advanced breast cancer who have not received any prior endocrine-based treatment for metastatic disease. Patients may have received up to one prior line of chemotherapy for advanced disease.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Treatment should continue until unacceptable toxicity or disease progression.</li> <li>Patients should have a good performance status and not be resistant to prior (neo) adjuvant aromatase inhibitor therapy (i.e. have the potential to benefit from first-line endocrine based therapy), without active or uncontrolled metastases to the central nervous system.</li> <li>Patients will be eligible for either ribociclib plus an aromatase inhibitor in the first line setting or everolimus plus exemestane as a subsequent line of therapy, but not both therapies. Patients eligible include:               <ul style="list-style-type: none"> <li>Pre and peri-menopausal patients (should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist)</li> <li>Males</li> <li>Patients with bone-only metastases</li> <li>Patients who are HER2 equivocal by FISH testing (these patients are HER2 negative)</li> <li>Patients currently receiving first line aromatase inhibitor monotherapy for ER positive, HER2-negative metastatic breast cancer may have ribociclib added provided the above criteria is met.</li> </ul> </li> </ul> <p><b>HR Positive, HER2-Negative Advanced or Metastatic Breast Cancer in Combination With Fulvestrant</b></p> <ul style="list-style-type: none"> <li>In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER 2 negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. Patients may have also received up to one prior line of chemotherapy for advanced disease. Patients should have a good performance status, without active or uncontrolled metastases to the central nervous system and can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist).</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Treatment should continue until unacceptable toxicity or disease progression.</li> <li>Patients who progress <math>\leq</math> 12 months from (neo) adjuvant therapy are eligible for treatment with ribociclib plus fulvestrant.</li> <li>Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with palbociclib with fulvestrant.</li> </ul>				



Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Kisqali (ribociclib)</b>	200mg Tab	02473569	DNP	E (SFC)	NVR
Criteria	<ul style="list-style-type: none"> <li>Patients currently receiving fulvestrant monotherapy, and who have not progressed may have ribociclib added, provided they are CDK 4/6 inhibitor naïve and otherwise meet funding criteria.</li> <li>Patients who previously received everolimus plus exemestane will be eligible for funding of palbociclib plus fulvestrant on progression, provided that treatment was started prior to funding of CDK 4/6 + fulvestrant, patient must be CDK 4/6 naïve and otherwise meet funding criteria.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Maviret (glecaprevir/ pibrentasvir)</b>	100mg/40mg Tab	02467550	DNP	E (SF)	ABV
Criteria	<ul style="list-style-type: none"> <li>For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:</li> </ul>				
					<b>Approval Period</b>
	<b>Genotypes 1, 2, 3, 4, 5 or 6</b> <ul style="list-style-type: none"> <li>Treatment-naïve</li> </ul>				8 weeks
	<b>Genotypes 1, 2, 4, 5 or 6</b> <ul style="list-style-type: none"> <li>Treatment-experienced with regimens containing peginterferon/ribavirin (PR) and/or sofosbuvir (SOF)</li> </ul>				8 weeks (12 weeks with cirrhosis)
	<b>Genotype 1</b> <ul style="list-style-type: none"> <li>NS5A inhibitor treatment-naïve and treatment-experienced with regimens containing: <ul style="list-style-type: none"> <li>Boceprevir/PR; or</li> <li>Simeprevir (SMV)/SOF; or</li> <li>SMV/PR; or</li> <li>Telaprevir/PR</li> </ul> </li> </ul>				12 weeks



Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Maviret (glecaprevir/ pibrentasvir)	100mg/40mg Tab	02467550	DNP	E (SF)	ABV
Criteria	<b>Genotype 1</b> <ul style="list-style-type: none"> <li>NS3/4A inhibitor treatment-naïve and treatment-experienced with regimens containing:               <ul style="list-style-type: none"> <li>Daclatasvir (DCV)/SOF; or</li> <li>DCV/PR; or</li> <li>Ledipasvir/SOF</li> </ul> </li> </ul>			16 weeks	
	<b>Genotype 3</b> <ul style="list-style-type: none"> <li>Treatment-experienced with regimens containing PR and/or SOF</li> </ul>			16 weeks	
	<ul style="list-style-type: none"> <li>The following information is also required:               <ul style="list-style-type: none"> <li>Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5 or 6</li> <li>Quantitative HCV RNA value within the last 6 months</li> <li>Fibrosis stage</li> </ul> </li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>Acceptable methods for the measurement of fibrosis score include Fibrotest, liver biopsy, transient elastography (FibroScan®), serum biomarker panels (such as AST-to-Platelet Ratio Index or Fibrosis-4 score) either alone or in combination.</li> </ul> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Must be prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection).</li> <li>Claims will be limited to a 28-day supply.</li> </ul>				

# PharmacareNEWS

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### Nova Scotia Formulary Updates

#### New Exception Status Benefits

- Cresemba (isavuconazole)
- Triamcinolone Hexacetonide
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#### Non-Insured Product

Influsplit Tetra German-Labelled  
Influenza Vaccine

## Nova Scotia Formulary Updates

### New Exception Status Benefits

The following products have been listed with the following criteria, effective **immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Cresemba</b> <b>(isavuconazole)</b>	100mg Cap	02483971	DNP	E (SFC)	AVI
	200mg Vial	02483998	DNP	E (SFC)	AVI

#### Criteria

- For the treatment of adult patients with invasive aspergillosis who have a contraindication, intolerance or have failed to respond to oral voriconazole and caspofungin.
- For the treatment of adult patients with invasive mucormycosis.

#### Claim Notes:

- Must be prescribed by a hematologist or specialist in infectious diseases or medical microbiology.
- Initial requests will be approved for a maximum of 3 months.
- Claims for Cresemba 200mg Vial that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions using the DIN first and then the following PIN:
  - 00904516

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Triamcinolone Hexacetonide	20mg/mL Inj	02470632	DNP	E (F)	MDX
Criteria	<ul style="list-style-type: none"> <li>For the treatment of juvenile idiopathic arthritis.</li> </ul>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Xarelto (rivaroxaban)	2.5mg Tab	02480808	DNP	E (SF)	BAY
Criteria	<p>For use in combination with acetylsalicylic acid (75 mg to 100 mg) for the prevention of atherothrombotic events<sup>1</sup> in patients with concomitant coronary artery disease (CAD) and peripheral artery disease (PAD) who meet the following criteria:</p> <ul style="list-style-type: none"> <li>Patients with CAD are defined as having one or more of the following:               <ul style="list-style-type: none"> <li>Myocardial infarction within the last 20 years.</li> <li>Multi-vessel CAD (i.e., stenosis of <math>\geq 50\%</math> in two or more coronary arteries, or in one coronary territory if at least one other territory has been revascularized) with symptoms or history of stable or unstable angina.</li> <li>Multi-vessel percutaneous coronary intervention.</li> <li>Multi-vessel coronary artery bypass graft surgery.</li> </ul> </li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>Patients with CAD as defined above, must also meet one of the following criteria:               <ul style="list-style-type: none"> <li>Aged 65 years or older; OR</li> <li>Aged younger than 65 years with documented atherosclerosis or revascularization involving at least two vascular beds (coronary and other vascular) or at least two additional risk factors (current smoker, diabetes mellitus, estimated glomerular filtration rate <math>&lt; 60</math> mL/min, heart failure, non-lacunar ischemic stroke 1 month or more ago).</li> </ul> </li> <li>Patients with PAD are defined as having one or more of the following:               <ul style="list-style-type: none"> <li>Previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous transluminal angioplasty revascularization of the iliac or infrainguinal arteries.</li> <li>Previous limb or foot amputation for arterial vascular disease.</li> <li>History of intermittent claudication and one or more of the following: an ankle-brachial index of less than 0.90, OR significant peripheral artery stenosis greater than or equal to 50% documented by angiography or duplex ultrasound.</li> <li>Previous carotid revascularization or asymptomatic carotid artery stenosis greater than or equal to 50% diagnosed by angiography or duplex ultrasound.</li> </ul> </li> </ul> <p><b>Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>Patients who have CAD or PAD alone; OR</li> </ul>				

New Exception Status Benefits Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Xarelto</b> (rivaroxaban)	2.5mg Tab	02480808	DNP	E (SF)	BAY
Criteria	<ul style="list-style-type: none"> <li>• In patients with any one of the following characteristics:               <ul style="list-style-type: none"> <li>○ At high risk of bleeding.</li> <li>○ A history of stroke within one month of treatment initiation or any history of hemorrhagic or lacunar stroke.</li> <li>○ Severe heart failure with a known ejection fraction less than 30% or New York Heart Association class III or IV symptoms.</li> <li>○ An estimated glomerular filtration rate less than 15 mL/min.</li> <li>○ Require dual antiplatelet therapy, other non-ASA antiplatelet therapy, or oral anticoagulant therapy.</li> </ul> </li> </ul> <p><b>Clinical Notes:</b></p> <ol style="list-style-type: none"> <li>1. Atherothrombotic events include stroke, myocardial infarction, cardiovascular death, acute limb ischemia and mortality.</li> </ol>				

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Ziextenzo</b> (pegfilgrastim)	10mg/mL Inj	02497395	DNP	E (SFC)	SDZ
Criteria	<ul style="list-style-type: none"> <li>• For the prevention of febrile neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy with curative intent who:               <ul style="list-style-type: none"> <li>○ are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; or</li> <li>○ have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or</li> <li>○ have had a dose reduction, or treatment delay greater than one week due to neutropenia.</li> </ul> </li> </ul> <p><b>Clinical Note:</b></p> <ul style="list-style-type: none"> <li>• Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.</li> </ul>				

## Criteria Updates

The following criteria has been updated **effective immediately**.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
<b>Xtandi (enzalutamide)</b>	40mg Cap	02407329	DNP	E (SFC)	ASL
Criteria	<p><b>Metastatic Castration-Resistant Prostate Cancer (mCRPC)</b></p> <ul style="list-style-type: none"> <li>For the treatment of patients with metastatic castration-resistant prostate cancer.</li> </ul> <p><b>Clinical Notes:</b></p> <ol style="list-style-type: none"> <li>Patients should have a good performance status and no risk factors for seizures.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol> <p><b>Claim Notes:</b></p> <ul style="list-style-type: none"> <li>Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide.</li> </ul> <p><b>Non-Metastatic Castration-Resistant Prostate Cancer (nmCRPC)</b></p> <ul style="list-style-type: none"> <li>In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastases<sup>1</sup>.</li> <li>Patients should have a good performance status and no risk factors for seizures. Treatment should continue until unacceptable toxicity or radiographic disease progression.</li> </ul> <p><b>Clinical Notes:</b></p> <ul style="list-style-type: none"> <li>Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA &gt; 2 ng/mL.</li> <li>Castrate levels of testosterone must be maintained.</li> <li>Patients with N1 disease, pelvic lymph nodes &lt; 2cm in short axis located below the common iliac vessels are eligible for enzalutamide.</li> <li>Enzalutamide will not be funded for patients who experience disease progression on apalutamide.</li> <li>Patients receiving enzalutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC.</li> </ul> <p><sup>1</sup>High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT</p>				

## Criteria Updates Continued...

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Zytiga (abiraterone)	250mg Tab	02371065	DNP	E (SFC)	JAN
	500mg Tab	02457113	DNP	E (SFC)	JAN
Criteria	<ul style="list-style-type: none"> <li>For the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).</li> </ul> <p><b>Clinical Notes:</b></p> <ol style="list-style-type: none"> <li>Patients should have a good performance status.</li> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity.</li> </ol>				

## New Products

Effective **immediately**, the following new products have been added to the Nova Scotia Formulary. The benefit status within the Pharmacare Programs is indicated.

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Amlodipine	2.5mg Tab	02492199	DNP	SF	JPC
Mezera	1g/ACT Foam Enema	02474026	DNP	SF	AVI
Mezera	1g/Supp	02474018	DNP	SF	AVI

## Non-Insured Product

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

PRODUCT	STRENGTH	DIN	PRESCRIBER	BENEFIT STATUS	MFR
Dovato	50mg/300mg Tab	02491753	N/A	<b>Not Insured</b>	VIV

## Influsplit Tetra German-Labelled Influenza Vaccine in Pre-Filled Syringes (PFS)

GlaxoSmithKline Inc. has received approval from Health Canada for the importation and release of a limited supply of German-labelled Influsplit Tetra influenza vaccine pre-filled syringes to mitigate the shortages of influenza vaccines in Canada.

It is important to note that both GSK's FluLaval Tetra Canadian-Labelled MDV and Influsplit Tetra German-Labelled PFS are indicated for active immunization in persons 6 months of age and older for the prevention of disease caused by influenza virus types A and B contained in the vaccine, and are administered by intramuscular (IM) injection. FluLaval Tetra and Influsplit Tetra both contain the same strains for the 2020-2021 influenza season.

Pharmacists should be aware of the differences of composition and product labeling between the two vaccines and are directed to consult and use the information provided by the Provincial Bio-Depot with each order of Influsplit Tetra.

Claims table on Page 6.

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

CPHA CLAIM STANDARD FIELD #	CPHA CLAIM STANDARD FIELD NAME	CONTENT
D.56.03	DIN/GP#/PIN	<b>DIN</b> - Influsplit Tetra (German) 96599948 <b>PIN for pregnant women</b> - Influsplit Tetra (German) 96599947 <b>PIN for second dose for children</b> - Influsplit Tetra (German) 96599946
D.58.03	Quantity	000001 (one)
D.61.03	Prescriber ID	Pharmacists prescriber ID
D.66.03	Drug Cost/Product Value	DDDDD (dollar value - not adjudicated)
D 67.03	Cost Upcharge	DDDDD (dollar value- not adjudicated)
D.68.03	Professional Fee	\$12.40 until March 31, 2021 \$12.55 effective April 1, 2021





# PharmacareNEWS

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## **Nova Scotia Formulary Updates**

### **Dispensed Quantities: Prescriber Letters**

Letters from prescribers that are held on file and used to authorize future changes to a beneficiary's prescriptions, such as changes to quantity or days supply, will not be accepted by Pharmacare for any new prescription or refill claims after February 1, 2021. Prescribers must be intentional in the quantity and days supply they indicate on each new prescription and any changes to the prescription must be clearly documented as per Pharmacare requirements. Changes to prescriptions that are not authorized and documented as per the requirements in the Pharmacy Guide will be subject to recovery during audit.

### **Virtual Care Update**

#### **Claims Eligibility Extended to March 31, 2021**

The waiver of the in-person requirement for delivery of publicly funded assessment and prescribing services has been extended to March 31, 2021. The new virtual care eligibility and claims submission criteria for medication reviews for Pharmacare beneficiaries have also been extended to March 31, 2021. All provisions in the updated Pharmacy Guide pertaining to virtual care apply only until that date or until such time as a change to the date is communicated through the Pharmacare News Bulletin.

#### **Criteria Codes Required for All Pharmacy Service Claims**

As communicated in the November bulletin, to support monitoring and evaluation of virtual pharmacy services to inform development of a DHW policy on virtual care, all DHW-funded service claims require criteria codes effective December 1, 2020. The code ED must be entered in the Intervention Code field and one of the following codes must be entered in the Special Authorization Code field for all service claims:

- 91 = In-person
- 92 = Telephone
- 93 = Video

## Updates to the Nova Scotia Pharmacy Guide

The Nova Scotia Pharmacy Guide has been updated and the latest version can be found online at:

<https://novascotia.ca/dhw/pharmacare/pharmacy-guide.asp>. Updates include the following:

- Reference documents are no longer embedded in appendices. These previous appendices have been replaced by a new **Appendix 1** that provides links to current versions of all documents.
- A new **Publication History** section has been added at the end of the Guide to summarize the content changes in each version of the Guide.
- In the sections on **Advanced Medication Review Service, Basic Medication Review Service** and **Medication Follow-up Review Service**, new claims submission and documentation requirements to support virtual care delivery have been incorporated.
- A new section on **Virtual Care Delivery of Medication Reviews** has been added.
- In the section **Administration of Publicly Funded Influenza Vaccinations by Pharmacists**, eligibility has been expanded to include administration of the vaccine by a pharmacy technician with instruction incorporated on how such claims should be billed to DHW. PINs have been added for Influsplit Tetra products.
- In the section **Assessment and Prescribing for Uncomplicated Cystitis, Herpes Zoster and Contraception Management**, new claims submission requirements pertaining to virtual care delivery have been incorporated.
- In the section on **Prescription Renewals**, additional information has been provided on expected duration of therapy for publicly funded services and new claims submission requirements pertaining to virtual care delivery have been incorporated.
- In the **Audit** section of the Guide, in the section on **Required Documentation for Pharmacare Prescription Audits**:
  - Direction has been incorporated on acceptable practices for managing missing prescription dates, which is in line with the previous direction on handling incomplete patient names.
  - Verbal order documentation requirements for computer-generated prescriptions have been clarified.
  - Direction has been added that letters from prescribers authorizing changes to a patient's prescriptions are not accepted.
- In the **Audit** section of the Guide, in the section on **Pharmacare Prescription Audit Recovery Procedures**:
  - Audit recovery procedures pertaining to medication review services have been updated to reflect new virtual care requirements.
- In the **Audit** section of the Guide, in the section on **Pharmacy Service Audits**, in the section on **Required Documentation**:
  - The requirements for documenting a patient's consent for the service have been expanded to clarify that documentation must clearly and directly indicate consent was provided.

**Updates to the Nova Scotia Pharmacy Guide Continued...**

- In the **Audit** section of the Guide, in the section on **Pharmacy Service Audit Recovery Procedures**:
  - Related to the clarification on documenting consent, audit recovery procedure 5 has been updated.
  - For audit recovery procedure 9 pertaining to services that result in a prescription, a footnote has been added to indicate the requirement for prescribing notification has been waived until further notice.