Bulletin # 1051

April 22, 2021

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective April 22, 2021.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Existing Special Authorization Benefit Additions
- Benefit Status Changes
- Update on Quantity for Claims Submission

If you have any questions, please contact our office at 1-800-332-3691.

The Formulary Updates are available online: http://www.gnb.ca/0212/BenefitUpdates-e.asp. To unsubscribe from the NB Drug Plans email announcements, please send a message to info@nbdrugs-medicamentsnb.ca.

Regular Benefit Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Fluticasone Propionate (Aermony Respiclick™)	55 mcg / actuation powder for inhalation	02467895	TEV	ADEFGV	MLP
	113 mcg / actuation powder for inhalation	02467909			
	232 mcg / actuation powder for inhalation	02467917			
Gatifloxacin (Zymar® and generic brand)	0.3% ophthalmic solution	See NB Drug Plans Formulary or MAP List for Products		ADEFGV	MAP
Moxifloxacin (Vigamox® and generic brands)	0.5% ophthalmic solution	See NB Drug Plans Formulary or MAP List for Products		ADEFGV	MAP
Vortioxetine (Trintellix®)	5 mg tablet	02432919	VLH	ADEFGV	MLP
	10 mg tablet	02432927			
	20 mg tablet	02432943			
Special Authorization No Longer Required					
Ciprofloxacin/Dexamethasone (Ciprodex® and generic brand)	0.3% / 0.1% otic suspension	See NB Drug Plans Formulary or MAP List for Products		ADEFGV	MAP
Iron Sucrose (Venofer® and generic brand)	20 mg/mL vial	See NB Drug Plans Formulary or MAP List for Products		ADEFGV	MAP

Special Authorization Benefits Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Iron isomaltoside 1000 (Monoferric™)	100 mg/mL single-use vial	02477777	PFI	(SA)	MLP
	For the treatment of iron deficiency anemia in patients who • are intolerant to oral iron replacement products, or • have not responded to an adequate trial of oral iron.				
Salbutamol (pms-Salbutamol)	0.5 mg/mL solution for inhalation	02208245	PMS	W (SA)	MAP
	For patients who have tried using an inhaler with spacer device and • are unable to follow instructions, hold the spacer device or hold the device long enough to actuate it due to cognitive or physical limitations; or				

- have difficulty generating adequate inspiratory effort to achieve therapeutic benefit.

Claim Notes:
- Initial approval period: 1 year.
- Renewal approval period: Long term.

Sebelipase alfa (Kanuma™)	20 mg vial	02469596	ALX	(SA)	MLP

For the treatment of patients with lysosomal acid lipase (LAL) deficiency. For the complete criteria, please contact the NB Drug Plans at 1-800-332-3691.

Changes to Existing Special Authorization Benefits

Product	Strength	DIN	MFR	Plans	Cost Base
New Indication					
Olaparib (Lynparza®)	100 mg tablet 150 mg tablet	02475200 02475219	AZE	(SA)	MLP

1. As monotherapy maintenance treatment for adult patients with newly diagnosed advanced BRCA-mutated (germline or somatic) high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:
   - Complete or partial response to first-line platinum-based chemotherapy
   - Received at least four cycles of platinum-based chemotherapy
   - Last cycle of platinum-based chemotherapy completed within the previous 12 weeks

   Initial renewal criteria:
   - Written confirmation that the patient has a partial response or stable disease at two years.
   - Renewal requests will not be considered for patients who have no evidence of disease at two years.

   Subsequent renewal criteria:
   - Written confirmation that there is no evidence of disease progression.

   Clinical Notes:
   1. Imaging to rule out disease progression is required if maintenance therapy is initiated more than 8 weeks after the last cycle of platinum-based chemotherapy and/or if olaparib is interrupted for more than 14 days.
   2. Patients must have a good performance status.
   3. Treatment should continue until unacceptable toxicity, disease progression, or completion of two years of therapy, whichever occurs first.

   Claim Notes:
   - Requests for olaparib in combination with bevacizumab will not be considered.
   - Initial approval period: 2 years.
   - Renewal approval period: 1 year.

2. As monotherapy maintenance treatment for adult patients with platinum-sensitive relapsed BRCA-mutated (germline or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:
   - Completed at least two previous lines of platinum-based chemotherapy
   - Received at least four cycles of the most recent platinum-based chemotherapy regimen
   - Complete or partial radiological response to the most recent platinum-based chemotherapy regimen

   Renewal Criteria:
   - Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

   Clinical Notes:
   1. Platinum-sensitive disease is defined as disease progression occurring at least 6 months after completion of platinum-based chemotherapy.
   2. Maintenance therapy should begin within 8 weeks of the last dose of platinum-based chemotherapy.
   3. Patients must have a good performance status.
   4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

   Claim Notes:
   - Requests for olaparib will not be considered for patients previously treated with a PARP-inhibitor.
   - Initial approval period: 1 year.
   - Renewal approval period: 1 year.

New Indication

Teduglutide (Revestive®)	5 mg vial	02445727	SHI	(SA)	MLP

For the ongoing treatment of patients with Short Bowel Syndrome (SBS) as a result of major intestinal resection (e.g. volvulus, vascular disease, cancer, Crohn's disease, injury, congenital disease) who meet the following criteria:

- For pediatric patients:
  - Cumulative lifetime duration of parenteral support (PS) must be at least 12 months
  - PS must provide more than 30% of caloric and/or fluid and electrolyte needs
  - Prior to initiating teduglutide, PS frequency and volume must be stable for at least three months or there must be no improvement in enteral feeding for at least three months
- For adult patients:
  - Dependency on parenteral support (PS) for a least 12 months
  - Prior to initiating teduglutide, PS required at least three times weekly to meet caloric, fluid and electrolyte needs and stable PS frequency and volume for at least one month

A request for coverage for continued treatment will be considered if the patient has achieved at least a 20% reduction in PS volume compared to baseline, while on teduglutide therapy.

Renewal Criteria:
- Has maintained at least a 20% reduction in PS volume from baseline at 12 months.

Clinical Note:

- PS is defined as parenteral nutrition which encompasses parenteral delivery of lipids, protein and/or carbohydrates to address caloric needs, and/or intravenous fluids which. addresses fluid and electrolyte needs of patients

Claim Notes:

- Must be prescribed by a gastroenterologist or an internal medicine specialist with a specialty in gastroenterology.
- Approval period: 1 year.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined here.

Revised Criteria

Aflibercept (Eylea®)

40 mg/mL solution for intravitreal injection	02415992	BAY	(SA)	MLP

Diabetic macular edema

For the treatment of patients with diabetic macular edema (DME) who meet all of the following criteria:

- clinically significant center-involving macular edema for whom laser photocoagulation is also indicated
- Best Corrected Visual Acuity of less than 20/32
- central retinal thickness greater than or equal to 250 micrometers

Claim Notes:

- An initial claim of up to two vials of aflibercept (1 vial per eye treated) will be automatically reimbursed when prescribed by an ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval Period: 1 year. Confirmation of continued response is required.

Neovascular (wet) age-related macular degeneration (AMD)

For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria:

- Best Corrected Visual Acuity (BCVA) is between 20/40 and 20/320
- the lesion size is less than or equal to 12 disc areas in greatest linear dimension
- there is evidence of recent (less than 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, or optical coherence tomography (OCT)

Discontinuation Criteria:

Aflibercept should be discontinued if any one of the following occurs:

- Reduction in BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology
- Reduction in BCVA of 30 letters or more compared to either baseline and/or best recorded level
- Evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.

Claim Notes:

- An initial claim of up to two vials of aflibercept (1 vial per eye treated) will be automatically reimbursed when prescribed by an ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval Period: 1 year.

Retinal vein occlusion (RVO)
For the treatment of macular edema secondary to central retinal vein occlusion (CRVO) or branch retinal vein occlusion (BRVO).

Claim Notes:

- An initial claim of up to two vials of aflibercept (1 vial per eye treated) will be automatically reimbursed when prescribed by an ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval Period: 1 year. Confirmation of continued response is required.

Revised Criteria

Dornase alfa (Pulmozyme®)	1 mg/mL solution for inhalation	02046733	HLR	(SA)	MLP

For the treatment of patients with cystic fibrosis with clinical evidence of lung disease (e.g., frequent pulmonary exacerbations, FEV1 less than 90% predicted, difficulty clearing secretions).

Claim Notes:

- Requests will be considered for individuals enrolled in Plans ABDEFGV
- Approval period: Long term.

Revised Criteria

Ranibizumab (Lucentis®)	10 mg/mL solution for intravitreal injection	02296810	NVR	(SA)	MLP

Diabetic macular edema
For the treatment of patients with diabetic macular edema (DME) who meet all of the following criteria:

- clinically significant center-involving macular edema for whom laser photocoagulation is also indicated
- Best Corrected Visual Acuity of less than 20/32
- central retinal thickness greater than or equal to 250 micrometers

Claim Notes:

- An initial claim of up to two vials of ranibizumab (1 vial per eye treated) will be automatically reimbursed when prescribed by an ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval Period: 1 year. Confirmation of continued response is required.

Neovascular (wet) age-related macular degeneration (AMD)
For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who meet all of the following criteria:

- Best Corrected Visual Acuity (BCVA) is between 20/40 and 20/320
- the lesion size is less than or equal to 12 disc areas in greatest linear dimension
- there is evidence of recent (less than 3 months) presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, or optical coherence tomography (OCT)

Discontinuation Criteria:
Ranabizumab should be discontinued if any one of the following occurs:

- Reduction in BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology
- Reduction in BCVA of 30 letters or more compared to either baseline and/or best recorded level
- There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits.

Claim Notes:

- An initial claim of up to two vials of ranibizumab (1 vial per eye treated) will be automatically reimbursed when prescribed by an ophthalmologist. If continued treatment is required, a request must be made through special authorization.
- Approvals will be for a maximum of 1 vial per eye every 30 days.
- Approval Period: 1 year.

Benefit Status Changes

Product	Strength	DIN	MFR	Plans	Cost Base
Delisted					
Chlordiazepoxide / clidinium (Librax®, Chlorax)	5 mg / 2.5 mg capsule	See NB Drug Plans Formulary or MAP List for Products			MAP

Effective April 22, 2021, chlordiazepoxide/clidinium 5 mg / 2.5 mg capsules will be delisted as a benefit under the New Brunswick Drug Plans Formulary.

Although Librax® has been approved by Health Canada for the treatment of irritable bowel syndrome since 1961, the evidence for efficacy is limited and outweighed by the risk serious adverse reactions.

For patients who had a claim paid for chlordiazepoxide/clidinium between October 22, 2020 and April 22, 2021, chlordiazepoxide/clidinium will continue to be a benefit until October 22, 2021. After October 22, 2021, a special authorization request, documenting the rationale for continued use, will be required on an annual basis for coverage to be considered. New requests for special authorization will not be considered.

Delisted

Oxybutynin (pms-Oxybutynin)	2.5 mg tablet	02240549	PMS	MAP

Effective April 22, 2021, pms-Oxybutynin 2.5 mg tablets will be delisted as a benefit on the New Brunswick Drug Plans Formulary. Requests for special authorization will not be considered.

Patients who had a claim paid between October 22, 2020 and April 22, 2021 will continue to have coverage. Oxybutynin 5 mg tablets are listed as a regular benefit on the New Brunswick Drug Plans Formulary.

Update on Quantities for Claims Submission

Effective April 22, 2021, the quantity for claims submission will be changing for the following drugs:

Drug	Quantity for Claims Submission
Olodaterol and tiotropium bromide (Inspiolto Respimat®)	inhalation
Tiotropium bromide (Spiriva® Respimat®)	inhalation
Risankizumab (Skyrizi®)	syringe
Sarilumab (Kevzara®)	syringe / pen
Hydrocortisone / Pramoxine (Proctofoam-HC®)	application

This change will apply to all claims for prescriptions dispensed on, or after, April 22, 2021. Any claims for prescriptions dispensed prior to this date must follow the previous quantity for claim submission requirement.

Please refer to the Maximum Allowable Price (MAP) List and Manufacturers List Price (MLP) List at Drug Price Lists and Pricing Policy to confirm the correct quantity for claim submissions for a specific product.