Bulletin # 955

August 15, 2017

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective August 15, 2017.

Included in this bulletin:

- Regular Benefit Additions
- Special Authorization Benefit Additions
- Changes to Existing Special Authorization Benefits
- Benefit Status Changes
- Drugs Reviewed and Not Listed

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

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

Regular Benefit Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Clindamycin (Dalacin Vaginal Cream)	20mg/g vaginal cream	02060604	PAL	ADEFGV	MLP
Metronidazole (Nidagel®)	0.75% vaginal gel	02125226	VLN	ADEFGV	MLP

Special Authorization Benefit Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Elvitegravir/cobicistat/ emtricitabine/tenofovir alafenamide (Genvoya®)	150mg/150mg/200mg/10mg tablet	02449498	GIL	(SA)	MLP

For the treatment of HIV-1 infection in patients 12 years of age and older (weighing ≥ 35kg) with no known mutations associated with resistance to the individual components of Genvoya.

Claim Note:

- Prescriptions written for beneficiaries of Plan U by NB infectious disease specialists and medical microbiologists experienced in treating patients with HIV/AIDS, do not require special authorization.

Methadone (Metadol-D®)	10mg/mL oral concentrate	02244290	PAL	(SA)	MAP

For the treatment of patients with opioid use disorder who are not taking other opioids.

Requests for coverage and pharmacy claims must meet the requirements in the NB Drug Plans policy on Methadone for the Treatment of Opioid Use Disorder

Claim Note:

- Approvals will be for a maximum of 200mg per day.

Peginterferon beta-1a (Plegridy™) starter pack	63mcg/0.5mL, 94mcg/0.5mL prefilled pen 63mcg/0.5mL, 94mcg/0.5mL prefilled syringe	02444402	BIG	(SA)	MLP
Peginterferon beta-1a (Plegridy™)	125mcg/0.5mL prefilled pen 125mcg/0.5mL prefilled syringe	02444399			

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical exacerbations and slow the progression of disability who meet the following criteria:

- Two disabling attacks/relapses of MS in the previous two years, and
- Ambulatory with or without aid (EDSS of less than or equal to 6.5)

Clinical Note:
- An attack/relapse is defined as the appearance of new or recurring 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.

Claim Notes:
- Requests will be considered for individuals enrolled in Plans ADEFGV.
- Prescriptions written by New Brunswick neurologists do not require special authorization.

Changes to Existing Special Authorization Benefits

Product	Strength	DIN	MFR	Plans	Cost Base
New Indication					
Adalimumab (Humira®)	40mg/0.8mL pre-filled pen 40mg/0.8mL pre-filled syringe	02258595	ABV	(SA)	MLP

- For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 , and are:
  - refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
  - corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year).
- Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
  - a decrease in the partial Mayo score ≥ 2 from baseline, and
  - a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:
1. Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).
2. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
3. 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.

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 160mg followed by 80mg two weeks later, then 40mg every two weeks.

- Initial Approval: 8 weeks.
- Renewal Approval: 1 year.

Revised Criteria

Methadone (Metadol®)	1mg/mL oral solution	02247694			
	10mg/mL oral concentrate	02241377			
	1mg tablet	02247698			
	5mg tablet	02247699	PAL	(SA)	MLP
	10mg tablet	02247700			
	25mg tablet	02247701			

For the management of severe cancer-related or chronic non-malignant pain.

Changes in Metadol® Claim Submissions and Special Authorization Approvals

Effective September 5, 2017, claims for Metadol® must be billed using the applicable Drug Identification Number (DIN). Metadol® solution and concentrate will no longer be reimbursed for opioid use disorder and claims with the existing Product Identification Numbers (PINs) will not be accepted. Beneficiaries who have a current special authorization approval for opioid use disorder will have their approvals changed to Metadol-D®.

Benefit Status Changes

Product	Strength	DIN	MFR
Quinine sulfate (Apo-Quinine)	200mg capsule	02254514	APX
	300mg capsule	02254522	
Quinine sulfate (Novo-Quinine)	200mg capsule	00021008	TEV
	300mg capsule	00021016	
Quinine Sulfate	200mg capsule	00695440	ODN
	300mg capsule	00695459	
	300mg tablet	00695432	

Although quinine sulfate has been marketed in Canada since 1951, there have been ongoing safety concerns with its use. Quinine is only approved by Health Canada for the treatment of malaria. Despite this, quinine is widely used “off label” to treat and prevent nocturnal leg cramps.

The efficacy of quinine for leg cramps is limited and outweighed by the risk of serious adverse reactions that may require hospital admission or be life-threatening. These adverse reactions are unpredictable and may occur at any time, even in individuals who have been taking quinine on a chronic basis without problems. For a summary of adverse reactions associated with the use of quinine, please see the Health Canada Adverse Reaction Newsletter.

Given these safety concerns, **quinine will no longer be listed as a regular benefit effective September 1, 2017**. Prescribers and pharmacists may wish to discuss the safety warnings associated with quinine with their patients and review other ways to manage nocturnal leg cramps.

For patients who have had a claim paid for quinine between September 1, 2016 and August 31, 2017, quinine will continue to be a benefit until March 1, 2018. After March 1, 2018, a special authorization request, documenting the rationale for continued use, will be required for coverage to be considered.

Requests for special authorization will not be considered for new patients or patients who have not had a claim paid for quinine between September 1, 2016 and August 31, 2017.

Drugs Reviewed and Not Listed

The review of the following products found that they did not offer a significant therapeutic and/or cost advantage over existing therapies. Requests for special authorization will not be considered.

Product	Strength	DIN	MFR	Indication
Perindopril arginine/amlodipine (Viacoram®)	3.5mg/2.5mg tablet 7mg/5mg tablet 14mg/10mg tablet	02451530 02451549 02451557	SEV	Mild to moderate essential hypertension