Bulletin #903 March 23, 2015

NB Drug Plans Formulary Update

This update to the New Brunswick Drug Plans Formulary is effective March 23, 2015.

Included in this bulletin:

- Special Authorization Benefit Additions
- Submission of Claims over $9,999.99

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.

Special Authorization Benefit Additions

Product	Strength	DIN	MFR	Plans	Cost Base
Ledipasvir/sofosbuvir (Harvoni™)	90mg/400mg tablet	02432226	GIL	(SA)	MLP

For the treatment of chronic hepatitis C genotype 1 infection in adult patients.

Genotype 1	Approval Period
Treatment naïve patients with no cirrhosis, viral load < 6 million IU/mL	8 weeks
Treatment naïve patients with no cirrhosis, viral load ≥ 6 million IU/mL or Treatment naïve patients with compensated cirrhosis or Treatment-experienced patients with no cirrhosis	12 weeks
Treatment-experienced patients with compensated cirrhosis	24 weeks

Patients must also meet all of the following criteria:

1. Prescribed by a hepatologist, gastroenterologist or an infectious disease specialist (or other physician experienced in treating hepatitis C)
2. Lab-confirmed hepatitis C genotype 1
3. Patient has a quantitative HCV RNA value within the last 6 months
4. Fibrosis stage F2 or greater (Metavir scale or equivalent)

Exclusion Criteria:

- Patients currently being treated with another HCV antiviral agent.
- Patients who have previously received a treatment course of ledipasvir/sofosbuvir (re-treatment requests will not be considered).

Clinical notes:

1. For treatment naïve patients with no cirrhosis, viral load < 6 million IU/mL, evidence has shown that the SVR rates with the 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized as a Health Canada approved treatment option. Patients with severe fibrosis/borderline cirrhosis (F3-4) or HIV/HCV co-infected patients may be considered for 12 weeks coverage.
2. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score = A (5-6)
3. Treatment-experienced patients are patients who have previously been treated with peginterferon / ribavirin (PegIFN/RBV) regimen, including regimens containing HCV protease inhibitors and did not receive adequate response.
4. HIV-HCV co-infected patients may be considered as per criteria listed above.

Claim notes:

- Requests will be considered for individuals enrolled in Plans ADEFGV.
- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined below.

Pomalidomide (Pomalyst®)	1mg capsule	02419580	CEL	(SA)	MLP
	2mg capsule	02419599			
	3mg capsule	02419602			
	4mg capsule	02419610			

For the treatment of patients with relapsed and/or refractory multiple myeloma who:

- Have previously failed at least two treatments including both bortezomib and lenalidomide, and
- Demonstrated disease progression on the last treatment.

Clinical Note:

- Requests for pomalidomide will be considered in rare instances where bortezomib is contraindicated or when patients are intolerant to it; however, in all cases patients should have failed lenalidomide which they may have received in the maintenance setting.

Claim Note:

- Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions as outlined below.

Submission of Claims over $9,999.99

Claims that exceed the maximum claim amount of $9,999.99 must be divided and submitted as separate transactions on the same day. The fewest number of transactions must be used.

Transaction	DIN / PIN	Dispensing Fee	Quantity	Drug Cost	Days Supply	Copay
First	DIN	Yes	Adjust quantity so that claim cost (including the applicable drug cost, dispensing fee, mark-up) does not exceed $9,999.99	Up to MLP + up to 8% The amount must correspond to the quantity submitted in each transaction	Must correspond with the quantity being submitted in each transaction	Adjudication system will deduct copay from the first transaction only
Second	PIN	No				
Third (if required)	PIN	No				
Fourth (if required)	PIN	No				

The drugs and applicable DINs and PINs that are included in this policy are listed below.

Drug	Transaction and DIN / PIN			
	First DIN	Second PIN	Third PIN	Fourth PIN
Eculizumab (Soliris®) 10mg/mL vial	02322285	00994090	00994091	00994092
Ivacaftor (Kalydeco®) 150mg tablet	02397412	00903963	00903964	00903982
Ledipasvir / Sofosbuvir (Harvoni™) 400mg/90mg tablet	02432226	00904021	00904022	00904023
Lenalidomide (Revlimid®) 5mg capsule	02304899	00904000	00904001	00904024
Lenalidomide (Revlimid®) 10mg capsule	02304902	00904005	00904006	00904025

Lenalidomide (Revlimid®) 15mg capsule	02317699	00904010	00904011	00904026
Lenalidomide (Revlimid®) 25mg capsule	02317710	00904013	00904014	00904027
Pomalidomide (Pomalyst®) 1mg capsule	02419580	00904028	N/A	N/A
Pomalidomide (Pomalyst®) 2mg capsule	02419599	00904029	N/A	N/A
Pomalidomide (Pomalyst®) 3mg capsule	02419602	00904030	N/A	N/A
Pomalidomide (Pomalyst®) 4mg capsule	02419610	00904031	N/A	N/A
Simeprevir (Galexos™) 150mg capsule	02416441	00904018	00904019	00904020
Sofosbuvir (Sovaldi®) 400mg tablets	02418355	00904015	00904016	00904017

Claims submitted that do not comply with the above requirements are subject to audit and recovery.