BULLETIN

NO. 43

March 18, 2021

Benefit List Update

The following products have been added to the Newfoundland and Labrador Prescription Drug Program (NLPDP) benefit list effective March 17, 2021.

Special Authorization

LANADELUMAB (TAKHZYRO 300MG/2ML PRE-FILLED SYRINGE, 300 MG/2 ML Vial)

For prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age or older who have experienced at least three HAE attacks within any four-week period and required injectable treatment.

Renewal criteria:

- An assessment of a response to treatment should be conducted three months after initiating treatment with lanadelumab.
- A response to treatment is defined as a reduction in the number of HAE attacks for which acute injectable treatment was received within the initial three months of treatment with lanadelumab compared to the rate of attacks observed before initiating treatment with lanadelumab.
- Following the initial three-month assessment, patients should be assessed for continued response to lanadelumab every six months.
- Continued response is defined as no increase in the number of HAE attacks for which acute injectable treatment was received compared with the number of attacks observed prior to initiating treatment with lanadelumab.

Discontinuation criteria:

Treatment should be discontinued in patients who either respond inadequately or exhibit a loss of response, defined as follows:

- No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with lanadelumab compared to number of attacks observed before initiation treatment with lanadelumab.
- An increase in the observed number of HAE attacks for which acute injectable treatment was received before initiating treatment with lanadelumab.

Clinical Note:

- The pre-treatment attack rate must be provided for those patients already receiving long-term prophylactic treatment for HAE and intent to transition to lanadelumab.

Claim Notes:

- The patient must be under the care of a specialist experienced in the diagnosis and management of patients with angioedema.
- Lanadelumab should not be used in combination with other medications used for long-term prophylactic treatment of angioedema (e.g., C1-INH).
- Approvals will be for a maximum of 300 mg every two weeks.
- Initial approval period: 3 months
- Renewal approval period: 6 months.

If you have any questions concerning these changes, please feel free to contact the Pharmaceutical Services Division at 1-888-222-0533 or 709-729-6507.

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