

CRITERIA FOR STARTING PATIENTS ON LONG-ACTING FACTOR PRODUCTS AND MONITORING OF UTILIZATION

CRITERIA FOR USE OF LONG-ACTING FACTOR CATEGORY PRODUCTS-ELOCTATE AND ALPROLIX:

- Eloctate is intended only for patients with severe or moderate Hemophilia A who are on prophylaxis with standard factor concentrates or having frequent bleeding events.
- Alprolix is intended only for patients with severe or moderate Hemophilia B who are on prophylaxis with standard factor concentrates or having frequent bleeding events.
- Eloctate and Alprolix should not be used for the treatment of patients under the age of 12 as they are not approved for this indication in Canada.
- All patients receiving Eloctate or Alprolix must be under the care of a physician associated with a Canadian hemophilia treatment center.
- All patients receiving Eloctate or Alprolix will be required to record factor concentrate use in MyCBDR, iCHIP or provide written diaries of factor concentrate use.

Specific criteria for starting Eloctate or Alprolix:

1. Evidence that peripheral infusion of standard factor VIII or IX concentrates cannot be accomplished reasonably without the placement of a central line which could be avoided by using Eloctate / Alprolix;
2. Less than expected half-life of the standard factor VIII or IX concentrate currently used by the patient with no evidence of a Factor VIII or IX inhibitor;
3. Other appropriate criteria for starting patients (with consideration of the CADTH reports on Eloctate and Alprolix) would include:
 - a. To improve compliance with a prophylactic regimen of Eloctate / Alprolix for a **patient with severe or moderate hemophilia A or B currently on a prophylaxis regimen** with a standard factor concentrate;
 - b. To improve quality of life by using a prophylactic regimen of Eloctate / Alprolix for a **patient with severe or moderate hemophilia A or B currently on a prophylaxis regimen** with a standard factor concentrate;
 - c. To decrease frequent breakthrough bleeds by using a prophylactic regimen of Eloctate / Alprolix for a **patient with severe or moderate hemophilia A or B currently on a prophylaxis regimen** with a standard factor concentrate;
 - d. To decrease frequent bleeds by using a prophylactic regimen of Eloctate / Alprolix for a **patient with severe or moderate hemophilia A or B with frequent bleeding events currently using on-demand therapy** with a standard factor concentrate.
 - e. Other (hemophilia treating physician to provide rationale if other than those previously listed).