Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE

Antihemophilic factor (recombinant), Fc fusion protein (Eloctate)

Notes:

- *Examples of failures to meet clinical goals: continuation of spontaneous bleeds, inability to achieve appropriate trough level, inability to tolerate (intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation)

Initiation (new start) criteria: Non-formulary **antihemophilic factor (recombinant), Fc fusion protein (Eloctate)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient has a diagnosis of hemophilia A without inhibitors
- Prescribed for routine prophylaxis
- Previous treatment with formulary FVIII product (i.e. Kovaltry) with at least 150 documented exposure days with documented failure to meet clinical goals*
- Previous treatment with emicizumab-kxwh (Hemlibra) with at least 150 documented exposure days and documented failure to meet clinical goals*
- Previous treatment with recombinant, fc-vwf-xten fusion protein-ehtl (Altuviiio) with at least 150 documented exposure days with documented failure to meet clinical goals*
- Dose does not exceed 50 IU/kg no more frequently than every 4 days

Criteria for *current Kaiser Permanente members* already taking the medication who have not been reviewed previously: Non-formulary **antihemophilic factor (recombinant), Fc fusion protein (Eloctate)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient has a diagnosis of hemophilia A without inhibitors
- Prescribed for routine prophylaxis
- Previous treatment with formulary FVIII product (i.e. Kovaltry) with at least 150 documented exposure days with documented failure to meet clinical goals*
- Previous treatment with emicizumab-kxwh (Hemlibra) with at least 150 documented exposure days and documented failure to meet clinical goals*
- Previous treatment with recombinant, fc-vwf-xten fusion protein-ehtl (Altuviiio) with at least 150 documented exposure days with documented failure to meet clinical goals*
- Dose does not exceed 50 IU/kg no more frequently than every 4 days

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Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **antihemophilic factor (recombinant), Fc fusion protein (Eloctate)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient has a diagnosis of hemophilia A without inhibitors
- Prescribed for routine prophylaxis
- Previous treatment with formulary FVIII product (i.e. Kovaltry) with at least 150 documented exposure days with documented failure to meet clinical goals*
- Previous treatment with emicizumab-kxwh (Hemlibra) with at least 150 documented exposure days and documented failure to meet clinical goals*
- Previous treatment with recombinant, fc-vwf-xten fusion protein-ehtl (Altuviiio) with at least 150 documented exposure days with documented failure to meet clinical goals*
- Dose does not exceed 50 IU/kg no more frequently than every 4 days

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **antihemophilic factor (recombinant), Fc fusion protein (Eloctate)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Documentation of positive clinical response to Eloctate (e.g. decrease in at least 1 spontaneous bleed per month from baseline or improved pain scores resulting in improved quality of life)