Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCHEM044.1225	**HEMATOLOGICAL AGENTS** **HEMOPHILIA PROPHYLACTIC AGENTS** See Table 1 for medications covered by policy
Effective Date: 2/1/2026	**Review/Revised Date**: 04/25, 06/25, 11/25 (SAB)
Original Effective Date: 04/25	**P&T Committee Meeting Date**: 02/25, 04/25, 06/25, 12/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA)-Approved Indications

REQUIRED MEDICAL INFORMATION:
For initial authorization, all the following criteria must be met:

1. Use is for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
2. One of the following:
    a. For emicizumab-kxwh (Hemlibra®):
        i. Diagnosis of hemophilia A (congenital factor VIII deficiency)
    b. For marstacimab-hncq (Hympavzi™):
        i. Diagnosis of severe hemophilia A (congenital factor VIII deficiency) defined as pre-treatment factor VIII level less than 1 IU/dL or less than 1% of normal factor levels
        OR
        ii. Diagnosis of moderately severe to severe hemophilia B (congenital factor IX deficiency) defined as pre-treatment factor IX level less than 2 IU/dL or less than or equal to 2% of normal factor levels
    c. For concizumab-mtci (Alhemo®) or fitusiran (Qfitlia®):
        i. Diagnosis of hemophilia A (congenital factor VIII deficiency)
        OR
        ii. Diagnosis of hemophilia B (congenital factor IX deficiency)
3. For marstacimab-hncq (Hympavzi™) patient has documentation of no factor inhibitors indicated by one of the following inhibitor titer levels:

   a. For Hemophilia A: factor VIII inhibitor titer less than 0.6 Bethesda units (BU) per mL
   b. For Hemophilia B: factor IX inhibitor titer less than 0.6 Bethesda units (BU) per mL
4. For fitusiran (Qfitlia®), patient has documentation of both of the following criteria:
   a. Prescriber attestation of, or documentation of, antithrombin (AT) activity level equal to or greater than 60% prior to treatment initiation
   AND
   b. Documentation of or prescriber attestation of planned follow-up and monitoring with AT activity to adjust dose
5. Dose and frequency must be in accordance with FDA-approved labeling (see Table 2)
6. For requests for marstacimab-hncq (Hympavzi™), concizumab-mtci (Alhemo®), and fitusiran (Qfitlia®) for the treatment of Hemophilia A:
   a. Documented trial and failure, intolerance, or contraindication to emicizumab-kxwh (Hemlibra®)

Note: When the above criteria are met, the requested medication will be approved for the loading and maintenance dose regimens approved by the United States Food and Drug Administration (FDA). Doses or frequencies exceeding FDA-approved dosing are subject to audit and post-service denial.

For reauthorization or patients established on therapy (Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy)
1. Documentation of response to therapy indicating a beneficial response (such as disease stability or a reduction in bleeding events, in the severity of bleeding episodes, freedom from joint bleeding, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds)
2. Dose and frequency must be in accordance with FDA-approved labeling
3. For concizumab-mtci (Alhemo®), documentation of annual drug plasma concentration monitoring with appropriate dosage adjustments

EXCLUSION CRITERIA:
Use with other hemophilia prophylactic therapies (such as emicizumab-kxwh [Hemlibra®], marstacimab-hncq [Hympavzi™], concizumab-mtci [Alhemo®], fitusiran (Qfitlia®), or regular use of prophylactic factor products)

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication.

PRESCRIBER RESTRICTIONS:

Must be prescribed by, or in consultation with, a hematologist.

COVERAGE DURATION:
Hemlibra® - Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.
Alhemo®, Hympavzi™, Qfitlia®: Authorization and reauthorization will be approved for one year.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Emicizumab-kxwh (Hemlibra®) is a bispecific factor IXa- and factor X-directed antibody that bridges activated factor IX and factor X to restore the function of missing activated factor VIII that is needed for effective hemostasis.

- Recommended loading dose is 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by a maintenance dose of:
  - 1.5 mg/kg once every week, or
  - 3 mg/kg once every two weeks, or
  - 6 mg/kg once every four weeks.

Marstacimab-hncq (Hympavzi™) is a human monoclonal immunoglobulin G1 (IgG1) antibody directed against the Kunitz domain 2 (K2) of tissue factor pathway inhibitor (TFPI) to neutralize TFPI activity and enhance coagulation. TFPI blocks early phases of coagulation by inhibiting activated factor VII (FVIIa) and activated factor X (FXa). Marstacimab may be self-administered or caregiver-administered after proper training by a healthcare provider. The recommended dose for adult and pediatric patients 12 years of age and older is as follows:

- Loading dose: 300 mg (two 150 mg subcutaneous injections).

- Maintenance dosing: One week after the loading dose, initiate maintenance dosing of 150 mg once every week on the same day by subcutaneous injection.
- Dose adjustment: 300 mg subcutaneous injection weekly can be considered in patients weighing ≥50 kg when control of bleeding events is judged to be inadequate by the healthcare provider.

Concizumab-mtci (Alhemo®) is a humanized monoclonal immunoglobulin G1 (IgG4) antibody antagonist of endogenous TFPI. The inhibition of TFPI enhances activated factor X (FXa) production during the initiation phase of coagulation, which improves thrombin generation and clot formation. Concizumab may be self-administered or caregiver-administered after proper training by a healthcare provider. The recommended dose for adult and pediatric patients 12 years of age and older is as follows:

- Loading dose: 1 mg/kg on Day 1
- Maintenance dose: Once-daily dose of 0.2 mg/kg starting on Day 2
- Once the concizumab concentration result is available, individualize the maintenance dose no later than 8 weeks after initiation of treatment

Fitusiran sodium (Qfitlia®) is an antithrombin-directed double-stranded small interfering ribonucleic acid (siRNA) agent that causes degradation of antithrombin (AT) messenger RNA (mRNA) through RNA interference, reducing plasma AT levels. Fitusiran is provided in 20mg/0.2 ml single use vials.

- Starting dose: 50 mg once subcutaneously every two months and the dose and/or dosing interval is adjusted to maintain AT activity between 15-35% (see package insert for dose modifications).
- Once the patient's target dose is identified based on AT activity 15–35%, providers should measure AT activity annually. Additional AT measurements can be considered if bleeding control is not adequate.

FDA APPROVED INDICATIONS:

Emicizumab-kxwh (Hemlibra®) is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

Marstacimab-hncq (Hympavzi™) is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients 12 years of age and older with:

- Hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or
- Hemophilia B (congenital factor IX deficiency) without factor IX inhibitors

Concizumab-mtci (Alhemo®) is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with:

- Hemophilia A (congenital factor VIII deficiency) with or without FVIII inhibitors
- Hemophilia B (congenital factor IX deficiency) with or without FIX inhibitors

Fitusiran sodium (Qfitlia®) is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with

- Hemophilia A with or without factor VIII inhibitors
- Hemophilia B with or without factor IX inhibitors

POSITION STATEMENT:

- Hemophilia is an X-linked recessive genetic disorder caused by mutations in the genes that encode coagulation factors, leading to deficiencies in the proteins necessary for normal blood clotting. Specifically, hemophilia A is characterized by a deficiency in factor VIII (FVIII), while hemophilia B is caused by a deficiency in factor IX (FIX). Hemophilia primarily affects males, and it is estimated that between 30,000 and 33,000 males in the United States live with hemophilia A or B, with approximately 76% of them having hemophilia A. About 60% of these individuals have the severe form of the disorder. Individuals with hemophilia, particularly those with severe disease, are at risk for life-threatening bleeding, including intracranial hemorrhages. While bleeding often occurs following an injury, individuals with hemophilia may also experience frequent spontaneous bleeding episodes, most commonly into the joints or muscles.
- The severity of the disease is determined by the level of clotting factor in the blood and is typically classified as:
    - Mild disease: 5–40 IU/dL or 5%–40% of normal factor levels
    - Moderate disease: 1–5 IU/dL or 1%–5% of normal factor levels
    - Severe disease: <1 IU/dL or <1% of normal factor levels[4-6]
- Prophylaxis with plasma-derived or recombinant standard half-life factor, extended half-life factor, or non-factor replacement emicizumab (Hemlibra®) is the standard of care for preventing bleeding in patients with severe hemophilia. Treatment is typically initiated before the age of 3. Although all prophylaxis products effectively prevent bleeding, they differ in patient responses, safety profiles (including the risk of inhibitor development), costs, and product characteristics (such as half-life and effects on monitoring). The choice of prophylaxis is a team-based decision that considers the patient's specific circumstances and needs, with the primary goal of preventing bleeding.[9-11]

Marstacimab-hncq (Hympavzi™)

Clinical Trials:[7,8]

BASIS (NCT03938792- unpublished)

- Phase 3, open-label, multicenter, two-phase trail consisted of a 6-month observational phase (OP), during which participants were enrolled in two cohorts. One cohort, the on-demand (OD) treatment group, received factor replacement therapy as needed in response to bleeding symptoms, while the other cohort, the prior routine prophylactic (RP) treatment group, received scheduled or routine factor replacement therapy to prevent bleeds. This was followed by a 12-month active treatment phase (ATP) of marstacimab prophylaxis. Participants were all adult and pediatric males (N=116) 13 to 66 years old, weighing at least 35 kilograms, and with a diagnosis of severe hemophilia A (FVIII levels <1% of normal) without FVIII inhibitors or moderately severe to severe hemophilia B (FIX levels ≤2%) without FIX inhibitors.
- The primary endpoint was a non-inferiority test of annualized bleeding rate (ABR) during the 12-month ATP phase of marstacimab compared with the ABR of the OD and RP cohorts during the OP. Key secondary endpoints include the incidence of total bleeds, spontaneous bleeds, joint bleeds, and target joint bleed.
- Efficacy: The mean ABR for treated bleeds were 38 [95% CI: 31.03, 46.54] in the OD cohort and 7.85 [95% CI: 5.09, 10.61] in RP cohort during the OP. Following marstacimab treatment in the ATP, mean ABRs for treated bleeds were 3.18 [95% CI: 2.09, 4.85] in the OD cohort and 5.08 [95% CI: 3.40, 6.77] in the RP cohort, reflecting a 91.6% and 35.2% reduction over a 12-month ATP, respectively.
- Secondary endpoints:
    - Marstacimab prophylaxis demonstrated superiority over OD factor-based therapy and noninferiority to RP factor-based therapy in reducing spontaneous bleeds, joint bleeds, total bleeds, and target joint bleeds.

Comparison of ABRs with Marstacimab Prophylaxis vs Previous OD or RP

Marstacimab Prophylaxis vs. OD Factor-Based Therapy		**Marstacimab Prophylaxis vs. Previous Factor-Based RP**	
OD Factor-Based Therapy During 6-Month OP (N=33)	Marstacimab Prophylaxis, 12-Month ATP (N=33)	Factor-Based RP During 6-Month OP (N=83)	Marstacimab Prophylaxis, 12-Month ATP (N=83)
Treated Bleeds (Primary endpoint)			
38.00 (31.03, 46.54)	3.18 (2.09, 4.85)	7.85 (5.09, 10.61)	5.08 (3.40, 6.77)
Ratio vs. OD (95% CI), *P*-value		**Difference vs. RP (95% CI)**	
0.084 (0.059, 0.119), <0.0001		−2.77 (−5.37, −0.16)	
Spontaneous Bleeds, Treated			

30.93 (24.12, 39.67)	2.44 (1.61, 3.69)	5.86 (3.54, 8.19)	3.78 (2.25, 5.31)
Ratio vs. OD (95% CI), *P*-value		**Difference vs. RP (95% CI)**	
0.079 (0.054, 0.114), <0.0001		−2.09 (−4.23, 0.06)	
Joint Bleeds, Treated			
32.86 (26.15, 41.29)	2.83 (1.81, 4.44)	5.66 (3.33, 7.98)	4.13 (2.59, 5.67)
Ratio vs. OD (95% CI), *P*-value		**Difference vs. RP (95% CI)**	
0.086 (0.059, 0.125), <0.0001		−1.53 (−3.70, 0.64)	
Total Bleeds, Treated and Untreated			
47.76 (39.60, 57.60)	7.39 (5.08, 10.74)	8.84 (5.97, 11.72)	5.97 (4.13, 7.81)
Ratio vs. OD (95% CI), *P*-value		**Difference vs. RP (95% CI)**	
0.155 (0.116, 0.207), <0.0001		−2.87 (−5.61, −0.12)	
Target Joint Bleeds, Treated			
23.18 (17.20, 31.24)	1.84 (1.06, 3.17)	3.36 (1.59, 5.14)	2.51 (1.25, 3.76)
Ratio vs. OD (95% CI), *P*-value		**Difference vs. RP (95% CI)**	
0.079 (0.051, 0.124), <0.0001		−0.86 (−2.41, 0.70)	

- Adverse reactions in >3% of patients treated with marstacimab: injection site reaction (N=11, 9%), headache (N=8, 7%), and pruritus (N=4, 3%).
- There were no reported discontinuations due to adverse reactions, and no deaths or thrombotic or embolic events were observed.

Concizumab-mtci (Alhemo®)

Clinical Trials:[13]

explorer7 (PubMed ID #37646676)

- Phase 3, prospective, multicenter, open-label trial consisting of a 6- to 8- month active treatment phase. Participants were all adult and pediatric males (N=133) 12 to 79 years of age with a diagnosis of hemophilia A or B of any severity. All patients weighed at least 25 kilograms and had received treatment with bypassing agents (Eptacog alfa was used in explorer7) within the 24 weeks prior to screening. Individuals were excluded if they had a history, current signs or symptoms, or at high risk of thromboembolic events, ongoing or planned immune tolerance induction treatment, or planned major surgery.
- The primary endpoint was the annualized bleeding rate (ABR) of treated spontaneous and traumatic bleeding episodes in patients receiving concizumab prophylaxis compared to those receiving no prophylaxis.
- Efficacy: The mean ABR for treated bleeds was 1.7 [95% CI: 1.01, 2.87] in the concizumab prophylaxis group and 11.8 [95% CI: 7.03, 19.86] in the no prophylaxis group. This corresponds to an ABR ratio of 0.14 ($p < 0.001$), reflecting an 86% in bleeding episode with concizumab prophylaxis.

Comparison of ABRs with Concizumab Prophylaxis Versus No Prophylaxis

Outcome	Group 1, No Prophylaxis (N=19)	Group 2, Concizumab Prophylaxis (N=33)	ABR Ratio (95% CI)
Primary endpoint			
Treated spontaneous and traumatic bleeding episodes	11.8	1.7	0.14 (0.07-0.29) P<0.001
Treated bleeding episodes			
Spontaneous bleeding episodes	9.4	1.3	0.14 (0.06-0.30)
Joint bleeding episodes	9.1	1.4	0.15 (0.07-0.32)
Target joint bleeding episodes	1.1	0.1	0.12 (0.02-0.84)
All treated and untreated bleeding episodes	13.3	4.4	0.33 (0.17-0.64)

- Adverse reactions reported in ≥5% of patients treated with concizumab: injection site reactions (18%) and urticaria (6%)
- Permanent discontinuation due to an adverse reaction occurred in one patient due to a renal infarct

Fitusiran sodium (Qfitlia®)

Clinical Trials

- Moderate quality evidence based on two phase 3 clinical trials, ATLAS-A/B and ATLAS-INH, evaluating fitusiran in males equal to or greater than 12 years of age with severe hemophilia A or B, demonstrating a reduction in annualized bleeding rate (ABR) in the fitusiran group compared to on-demand bypassing agents/clotting factor concentrates (73% reduction in ABR in ATLAS-INH, p=0.0006; 71% reduction in ABR in ATLAS-A/B, p<0.0001).
- The long-term extension study ATLAS-OLE with patients rolled over from the ATLAS-A/B and ATLAS-INH study demonstrated a median observed ABR for treated bleeds of 3.7 (0.0; 7.5) overall, 1.9 (0.0; 5.6) in inhibitor patients and 3.8 (0.0; 11.2) in non-inhibitor patients.

ATLAS-INH (PubMed ID #NCT03417102)

- Patient population: patients (N=57) adult and pediatric males aged equal to or greater than 12 years with hemophilia A or B with inhibitory antibodies to factor VIII (FVIII) or factor IX (FIX), who previously received on-demand (episodic) treatment with bypassing agents (BPAs) for bleeding
    - Key inclusion criteria: with inhibitors
    - Key exclusion criteria: AT activity <60% at screening

- Intervention: patients were randomized in a 2:1 ratio to receive fitusiran prophylaxis at a fixed dose 80 mg subcutaneously once monthly (N=38) or BPA on-demand for treatment of breakthrough bleeding episodes (N=19)
    - Note: The 80 mg dose of fitusiran is not FDA approved because of an increased risk of serious thrombotic events, gallbladder events (including the need for cholecystectomy) and hepatotoxicity.
- Primary endpoint was annualized bleeding rate (ABR) for treating bleeds during efficacy period
- Efficacy:

Endpoint	fitusiran group (n =38)	On demand BPA group (n=19)
All Treated Bleeds		
ABR (95% CI)	5.1 (2.9, 9.5)	19.1 (11.8, 31.0)
% reduction; P-value	73%; p=0.0006	
Treated Spontaneous Bleeds		
ABR (95% CI)	3.1 (1.8, 5.4)	17.1 (9.9, 29.6)
% reduction; P-value	82%; <0.001	
Treated Joint Bleeds		
ABR (95% CI)	4.0 (2.5, 6.2)	14.4 (9.0, 23.1)
% reduction; P-value	73%; p=0.0001	

- Safety:
    - Most common treatment-emergent adverse events (TEAEs) in the fitusiran group were increased alanine aminotransferase (ALT), upper respiratory tract infection, nasopharyngitis, abdominal pain, increased aspartate aminotransferase (AST), cough, arthralgia, asthma, gastritis, and headache.
    - 15 participants (19.0%) in the fitusiran group experienced TEAEs with ALT or AST elevation >3 × upper limit of normal.
    - No TEAEs of suspected or confirmed thromboembolism were reported

ATLAS-A/B (PubMed ID #NCT03417245)

- Patient population: Patients (N=57) adult and pediatric males aged equal to or greater than 12 years with hemophilia A or B with inhibitory antibodies to factor VIII (FVIII) or factor IX (FIX), who previously received on-demand (episodic) treatment with bypassing agents (BPAs) for bleeding
    - Key inclusion criteria: without inhibitors
    - Key exclusion criteria: AT activity <60% at screening
- Intervention: patients were randomized 2:1 to receive either:
    - Fitusiran 80 mg subcutaneously once monthly

        - Note: The 80 mg dose of fitusiran is not FDA approved because of an increased risk of serious thrombotic events, gallbladder events (including the need for cholecystectomy) and hepatotoxicity.
    - On-demand clotting factor concentrates
- Primary endpoint was annualized bleeding rate (ABR) for treating bleeds during efficacy period.
- Efficacy

Endpoint	fitusiran group (n =80)	On demand BPA group (n=40)
All Treated Bleeds		
ABR (95% CI)	9.0 (5.6, 14.5)	31.4 (20.5, 48.2)
% reduction; P-value	71%; p<0.0001	
Treated Spontaneous Bleeds		
ABR (95% CI)	5.4 (3.7, 8.0)	21.0 (14.0, 31.6)
% reduction; P-value	74%; p<0.0001	
Treated Joint Bleeds		
ABR (95% CI)	6.2 (4.2, 9.2)	21.6 (14.6, 31.9)
% reduction; P-value	74%; p<0.0001	

- Safety
    - Most common treatment-emergent adverse events (TEAEs) in the fitusiran group included increased alanine aminotransferase (ALT), upper respiratory tract infection, nasopharyngitis, abdominal pain, increased aspartate aminotransferase (AST), cough, arthralgia, asthma, gastritis, and headache.
    - No treatment-related thromboembolic events or deaths were reported.

ATLAS-OLE (PubMed ID #NCT03754790)

- Patient population: Patients (N=227) adult and pediatric males age greater than or equal to 12 years with hemophilia A or B, with or without inhibitory antibodies to FVIII or FIX
    - Key inclusion criteria: Patients rolled over from ATLAS-INH and ATLAS-A/B and ATLAS-PPX, a crossover study in patients previously on CFC or BPA prophylaxis and were treated with fitusiran in ATLAS-OLE
    - Key exclusion criteria: AT activity <60% at screening
- Intervention:
    - Patients initially received fitusiran 80 mg subcutaneously once monthly. The study was amended to evaluate the efficacy and safety of the AT-DR.
    - In the AT-DR, the fitusiran starting dose was 50 mg every two months, and dosing was individually adjusted based on AT activity level using the INNOVANCE Antithrombin assay. The dose could be increased to 50 mg every month or 80 mg every month or decreased to 20 mg every two

months or 20 mg every month. Fitusiran was discontinued if AT activity was <15% at the lowest dose.

- Primary endpoint was annualized bleeding rate (ABR) for treating bleeds during efficacy period.
- Efficacy: The median observed annualized bleeding rate (IQR) for treated bleeds was 3.7 (0.0; 7.5) overall, 1.9 (0.0; 5.6) in inhibitor patients and 3.8 (0.0; 11.2) in non-inhibitor patients.
- Safety: Study dose of fitusiran amended due to an increased risk of serious thrombotic events, gallbladder events (including the need for cholecystectomy) and hepatotoxicity related to the 80 mg dose of fitusiran.

Table 1: BILLING GUIDELINES AND CODING

HCPCS	Coding Description	Brand Name
J7173	Injection, concizumab-mtci, 0.5 mg	Alhemo®
J7170	Injection, emicizumab-kxwh, 0.5 mg	Hemlibra®
J7172	Injection, marastacimab-hncq, 0.5 mg	Hympavzi™
J7174	Injection, fitusiran, 0.04 mg	Qfitlia®
ADMINISTRATION CODES◊		
96372	Ther/proph/diag inj sc/im	
96401	Chemo anti-neopl sq/im	

◊ Coding/Administration Notes:
• The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
• HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations

Table 2: FDA Approved dosing regimens

Medication	Dosage
Alhemo®	**Initial dosage:** 1 mg/kg once on day 1 (loading dose) then 0.2 mg/kg once daily starting on day 2; continue for 4 to 8 weeks, then maintenance dosage is based on plasma concentrations **Maintenance dose:** Dose adjustments based on plasma concentration: • <200 ng/mL – Increase dose to 0.25 mg/kg once daily • 200-4,000 ng/mL – continue 0.2 mg/kg once daily • >4,000 ng/mL – Decrease dose to 0.15 mg/kg once daily
Hemlibra®	**Initial dosage:** 3 mg/kg once weekly for 4 weeks

<table>
<tr><td></td><td>Maintenance dosing: 1.5 mg/kg once weekly or 3 mg/kg once every 2 weeks or 6 mg/kg once every 4 weeks</td></tr>
<tr><td>Hympavzi™</td><td>Initial dosage: 300 mg once (loading dose)
Maintenance dose: 150 mg once weekly starting one week after loading dose.
For patients ≥50 kg: If control of bleeding events is determined to be inadequate, consider an increase to 300 mg once weekly</td></tr>
<tr><td>Qfitlia®</td><td>Initial dosage: 50 mg once every 2 months
Maintenance dosage:
Based on antithrombin activity level at weeks 4, 12, 20, and 24:
<table>
<tr><th>Last Dosage Administered</th><th>Antithrombin Activity Level</th><th>Dose Modification</th></tr>
<tr><td rowspan="3">50 mg every 2 months</td><td>Less than 15%</td><td>20 mg every 2 months</td></tr>
<tr><td>15% to 35%</td><td>Continue current dosage</td></tr>
<tr><td>Greater than 35%</td><td>50 mg every month</td></tr>
<tr><td rowspan="3">20 mg every 2 months</td><td>Less than 15%</td><td>10 mg every 2 months</td></tr>
<tr><td>15% to 35%</td><td>Continue current dosage</td></tr>
<tr><td>Greater than 35%</td><td>20 mg every month</td></tr>
<tr><td rowspan="3">10 mg every 2 months</td><td>Less than 15%</td><td>Discontinue Qfitlia</td></tr>
<tr><td>15% to 35%</td><td>Continue current dosage</td></tr>
<tr><td>Greater than 35%</td><td>10 mg every month</td></tr>
</table></td></tr>
</table>

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