Hemophilia Factor Program

Standards of Care and Clinical Criteria for Use

FDA Indication and Usage

Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia

Control and prevention of bleeding episodes in adults and children with hemophilia

Perioperative management in adults and children with hemophilia

Dosage Form/Strength

Dosage and duration of treatment depend on the severity of the factor deficiency, the location/extent of bleeding, and the patient's clinical condition.

Criteria for Approval

- The patient has been diagnosed with one of the following conditions:
  - hereditary factor VIII deficiency
  - hereditary factor IX deficiency
  - von Willebrand disease
  - acquired hemophilia
  - other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors
- Prescriber is affiliated with the regional Hemophilia Treatment Center https://www2a.cdc.gov/ncbddd/htcweb/Dir_Report/Dir_Search.asp
- Enrolled Alaska Medicaid providers prescribing and dispensing clotting factor concentrates or clotting factor products agree to comply with standards of care as outlined in this and affiliated documents
- Authorizations will be approved in consideration of the treatment plan; submitted treatment plans must include defined prophylactic and on-demand regimens with defined infusion intervals and number of doses to be dispensed per fill
- Patients shall continue to log infusions; pharmacy provider is responsible for maintaining infusion logs and reviewing and identifying variances – compliance concerns, utilization frequency, etc. Infusion logs may be requested by the State prior to authorizing a new treatment plan or renewal authorization.

Authorizations

- Initial coverage may be approved for up to 3 months.
- *Subsequent re-authorizations* may be approved for longer periods if required clinical documentation submitted and clinical stability has been established.
- Authorizations shall be specific to the patient, prescriber, and pharmacy provider. In the event a patient switches prescribers or pharmacy providers, a formal transfer of authorization must be requested. Emergency one-time transfer of authorization overrides may be requested by the prescriber or the pharmacy provider through the Clinical Call Center in the event that a delay in treatment could adversely impact the patient's health and well-being.

Quantity Limit

- Based on treatment plan; individual dispensing not to exceed one month supply.
- Pharmacy providers may dispense hemophilia factor product within authorized amount based on prescribed treatment plan up to one month supply; dispensing of prophylactic and on-demand product shall not be combined in same claim.
- Dispensing tolerance ±5%.

Provider/Facility Adherence to Program Requirements

- Program requirements for prescribing and dispensing clotting factor concentrates to Alaska Medicaid members apply to any Alaska Medicaid enrolled providers involved in the prescribing, dispensing, and management of patients with a diagnosis outlined in the Criteria for Approval section.

Required Documentation for New Patients and Annual Certification Review

Providers prescribing clotting factor concentrates for medically necessary conditions to members not previously receiving clotting factor through Alaska Medicaid coverage, must submit the member intake form with treatment plan. Intake form must be signed by prescriber.

Prescribing providers are required to provide the following information for new patients, for current patients at least annually, and for current patients when there are changes:

- Member name.
- Alaska Medicaid member identification number.
- Member address, telephone number, and preferred contact method for notifications.
- Member date of birth.
- Gender.
- Height
- Weight
- Diagnosis
- Diagnosis confirmation
- Baseline and on-regimen factor levels.
- Disease severity
- Venous Access

- Inhibitor status/date
- Allergies
- Prescribed prophylaxis regimen with dosing instructions, frequency and quantity to be filled for one month supply
- Prescribed on-demand bleeding regimen with dosing instruction, frequency and quantity to be filled for episodic bleeding events.
- Prescribing provider
- Hemophilia Treatment Center

Prescriber Responsibilities

- Providers with the intent of prescribing clotting factor concentrate to Alaska Medicaid members are to be affiliated with the regional Hemophilia Treatment Center (HTC) within the region of the patient's residence.
    - Prescribers treating patients traveling outside of the patient's residence region are required to consult with the patient's home HTC prior to providing care unless doing so could cause a delay in treatment of the patient.
- Providers with the intent of prescribing clotting factor concentrate to Alaska Medicaid members are required to develop treatment plan with consideration of the following components:
    - Refer to Intake Form – Treatment Plan
- Prescribers retain ultimate prescriptive authority and treatment plan responsibility which includes product selection, frequency of administration, doses to be dispensed, and length of therapy.

Pharmacy Provider Responsibilities

- Pharmacy providers enrolled with Alaska Medicaid wishing to seek reimbursement for the dispensing of clotting factor products to members shall notify the department annually in writing of the pharmacy's intent to provide clotting factor products. Notification shall be made on or before July 1 of each calendar year in a manner and form approved by the department. If
- Dispensing pharmacy shall provide patient with designated pharmacy contact telephone number for reporting problems with a delivery or product.
- Pharmacist shall be available twenty-four hours a day, seven days a week, every day of the year, either on-site or on-call, to fill prescriptions for blood-clotting products.
- Pharmacy providers are required to establish and document processes ensuring patient access to clotting factor concentrates in emergency situations and shall communicate these processes to the patient. Emergency processes will be coordinated with the prescriber/HTC.
- Prescribed clotting factor must be filled within plus or minus 5% tolerance of prescribed dose unless variance requested.
- Pharmacy provider must have contact information available for a nurse or nursing service/agency with experience in providing infusion related nursing services or nursing services for bleeding disorder patients if the nursing services are not provided by the pharmacy.
- Home assessment:
    - Verification of appropriate and adequate storage
    - Inventory of clotting factor and supplies
    - Verification of access to a bio-hazardous waste disposal unit
    - Review of infusion/treatment records/logs

- Patient counseling or necessary education
- Unique communication challenges (i.e., literacy, no telephone, etc.)
- Unique delivery challenges that may impact how quickly factor is able to reach the patient in the event of an emergency (i.e., urban vs. rural, on-the-road vs. off-the-road, etc.)

Initiation of Dispensing & Delivery of Clotting Factor Concentrate and Supplies

- Patients may choose which Alaska Medicaid enrolled pharmacy provider they wish to supply their hemophilia factor provided that pharmacy has declared their intent to the department to provide clotting factor and agrees to the standards of care set forth by the department.
- Patient or caregiver must initiate the request of initial fill or refill of clotting factor concentrate.
  - Pharmacy providers may not auto fill prescriptions for clotting factor concentrate.
  - The date of patient request & authorization of shipment shall be documented in the pharmacy's prescription records.
  - Pharmacy provider must document clotting factor concentrate and supplies patient currently has on hand. Dispensing of product should equal a one-month supply minus stock-on-hand, except that a five day emergency on-hand supply may be permitted.
  - Pharmacy provider shall identify any unexpected variation from usual patterns of clotting factor concentrate utilization.
  - If a refill of a patient's prophylactic product is due and a refill has not been requested by the patient, the pharmacy provider shall contact the patient and determine if factor is due.
- Pharmacy provider shall ship and deliver clotting factor products as prescribed within two days of receiving a prescription or refill request for established patients.
- Pharmacy provider shall ship/deliver clotting factor products as prescribed within three days of receiving a prescription or refill request for new patients in nonemergency situations.
- Pharmacy provider shall deliver clotting factor products within 24 hours of notification of a need due to a current bleeding episode.
- Shipments and deliveries of clotting factor concentrate from the pharmacy to the member (including overnight deliveries) must use appropriate cold chain management and packaging practices to ensure proper temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements.
- Signature by the member or caregiver is required upon delivery.
  - Caregiver is defined as any family member or non-family person who is responsible for providing the member's health care needs.
  - The statement "signature on file" is not acceptable to allow delivery to a location that does not have an individual present to physically receive the delivery.
  - Provider may not instruct a delivery service to leave a package at a location where an individual is not present to receive the delivery.
- Pharmacy provider must maintain documentation of product NDC, lot, potency, and expiration for each dispensed product and supply the documentation upon request. See also 7 AAC 105.220-260.

Supply Requirements

Pharmacy providers enrolled with Alaska Medicaid to supply clotting factor products agree to make available all brands, assays, and vial sizes of FDA approved blood-clotting products – including both plasma-based and recombinant products – as prescribed for a patient by the HTC. A list of identified suppliers must be maintained at the pharmacy and available during inspection. Pharmacies are not required to purchase products before receiving a prescription. Instead, the pharmacy must have an identified supplier if a product is needed. In the event a pharmacy is unable to supply the prescribed product, the pharmacy shall contact the prescriber directly and refer the patient to an alternate pharmacy provider.

Emergencies and incidental bleeding episodes

Pharmacy provider shall report to the prescriber and/or HTC within one business day of learning of an incident such as a bleeding episode, trauma, planned elective surgery, or any other situation that indicates the need for follow up with the prescriber.

Prohibition of Billing for Drugs Used During Inpatient Hospital Stays

Pharmacy provider may not submit claims for Alaska Medicaid reimbursement of drugs, including clotting factor products, dispensed to a patient or to a hospital for use by the patient during an inpatient hospital stay.

Clotting Factor Concentrate Purchasing Records and Reporting Requirements

Pharmacy providers who receive Alaska Medicaid reimbursement for clotting factor concentrate products may be subject to audit at any time. Pharmacy providers are required to retain relevant documentation supporting adherence to the new program requirements and produce it for and/or submit it to Alaska Medicaid upon request. Alaska Medicaid may deny or recoup payment for services that fail to meet program requirements. Pharmacy provider must maintain documentation of product NDC, lot, potency, and expiration for each dispensed product. See also 7 AAC 105.220-260.

Upon request, providers are required to provide detailed copies of purchase invoices that document clotting factor concentrate inventory acquired and dispensed.

Product Recall/Withdrawal Notifications

Providers are required to participate in the National Patient Notification System for clotting factor concentrate recalls. Current and accurate contact information must be maintained with the National Patient Notification System. (http://www.patientnotificationsystem.org/index.asp)

Pharmacy provider must notify the patient and the prescriber within twenty-four hours after notification from the manufacturer or any state/federal entity of a recall or withdrawal of a concentrate or any ancillary infusion equipment/supplies.

- Notification is required only if the manufacturer or state/federal entity requires or recommends patient notification.
- Pharmacy provider must also obtain a prescription for an alternative product if a new or amended prescription is required to dispense or deemed necessary and appropriate by the prescriber.
- Pharmacy provider is required to retrieve and quarantine any recalled clotting factor concentrates, equipment, or supplies dispensed to the patient within seven calendar days of notifying the patient.

Patient Communication Requirements

Providers are required to counsel the patient, family, and/or caregiver in accordance with the OBRA '90 (Omnibus Budget Reconciliation Act of 1990) to encourage appropriate medication use, promote realistic therapy expectations, help patients manage or minimize adverse effects (including those that can be related to inhibitors), and encourage adherence.

Pharmacy provider and their representatives may not suggest to a patient or caregiver that the patient needs a specific brand of clotting factor concentrate other than that which was prescribed by the patient's prescriber. The prescriber shall determine the brand of clotting factor concentrate that is appropriate for the patient.

Pharmacy provider may not suggest that a patient needs a specific number of doses of clotting factor concentrate for elective procedures. Pharmacy provider is required to refer the patient to the prescribing provider and/or HTC to discuss dosing of clotting factor concentrates for elective procedures.

Pharmacy providers are prohibited from providing gifts or facilitating gift giving from another entity, including a charitable organization, to a patient, patient's family, and/or caregiver. Gifts are any gratuity, discount, entertainment, travel, transportation, hospitality, loan, forbearance, pharmacy provider-owned vehicle use, housing assistance, or other tangible or intangible item having more than a nominal monetary or in-kind value. The above activities and/or coercion of a patient or caregiver to utilize a specific pharmacy's services in exchange for monetary gifts or in-kind gifts or assistance shall be considered unprofessional conduct and will be addressed as a sanctionable action; refer to 7 AAC 105.400(6).

Provider Training/Continuing Education

Pharmacy providers engaged in dispensing or filling clotting factor products or who provide patient counseling on clotting factor products to bleeding disorder patients must have sufficient knowledge, experience, and training to perform the duties assigned.

- Pharmacists engaged in counseling bleeding disorder patients shall maintain at least two (2) continuing education hours related to blood-clotting factor concentrates, infusion treatment/therapy, or blood-clotting disorders or diseases within a two year review period.
- Nurses are required to obtain a minimum of four (4) continuing education hours per year specific to hemophilia or related blood clotting factor-related diseases.

Responsibilities				
	HTC/Prescriber	**HTC/Nurse Case Manager**	**Pharmacy Provider**	**Patient**

Patient Intake Form	• Diagnosis
	• Clinical Assessment
	• Treatment plan
	  o Prophylaxis Rx
	  o Acute bleed Rx
	•
		x	x	

Diagnosis	x			
Selection of clotting factor	x			
Prophylaxis regimen Rx	x			
Acute bleed regimen Rx	x			
Pharmacokinetic and dynamic monitoring (half-life and recovery)	x			
Educational Materials		x	x	
Dispensing variance	+/- 5%		+/- 5%	
Safe home delivery or shipment of clotting factor			x	
Emergency delivery within 24 hours of emergent request			x	
Ensure maintenance of 5 emergency doses			x	x
Maintenance of infusion logs			x	x
Emergency telephone support (24/7)			x	

Responsibilities				
	HTC/Prescriber	**HTC/Nurse Case Manager**	**Pharmacy Provider**	**Patient**
Annual CE requirements, hemophilia specific			• RPh – minimum 2 CEU/2 years • RN – minimum 4 CEU/year	
Case representative contact with patient/caregiver – monthly (prophylaxis)			• Patient status • Assessment of adherence • Incidence of adverse events • Incidence of supply/equipment malfunctions • Inventory evaluation (assess on-hand amount to determine next delivery date) • Confirmation of next delivery date • Notification of product recalls or withdrawals (quarantine, retrieval, alternate product)	• Contact pharmacy to request monthly refill of prophylactic doses
Case representative contact with patient/caregiver – on-demand (active bleed)		• Contact pharmacy to update any bleed management prescriptions and/or orders	• Contact HTC to confirm their awareness of active bleed in patient •	• Contact pharmacy to request refill of on-demand (active bleed) doses