

**Affected Programs:** BadgerCare Plus, Medicaid, SeniorCare, Wisconsin Chronic Disease Program  
**To:** Blood Banks, Pharmacies, HMOs and Other Managed Care Programs

## New Program Requirements for Dispensing Clotting Factor Concentrates

Effective for dates of service on and after January 1, 2015, ForwardHealth is implementing new program requirements for dispensing clotting factor concentrates. These program requirements are intended to integrate pharmacy providers into the care management of the member and support ongoing communication between the pharmacy providers and prescribers.

Effective for dates of service on and after January 1, 2015, ForwardHealth will require pharmacy providers to follow new program requirements for dispensing clotting factor concentrates. Pharmacy providers are required to retain documentation supporting adherence to the new program requirements and produce it for and/or submit it to ForwardHealth upon request. ForwardHealth may deny or recoup payment for services that fail to meet program requirements.

A member with a clotting disorder requires coordinated care among many clinical disciplines to ensure optimal health outcomes for the member. Ensuring proper use of clotting factor concentrates is an important means to achieve the goal of improved member care and health. Pharmacy providers are in a unique position to help manage this care for members. The new program requirements integrate pharmacy providers into the care management of the member and support ongoing communication between pharmacy providers and prescribers.

### Entities Affected by New Program Requirements

The new program requirements for dispensing clotting factor concentrates apply to any outpatient pharmacy providing clotting factor concentrates and dispensing services to the member. The pharmacy provider includes the entity's employees and representatives.

The new program requirements in this *ForwardHealth Update* affect the following programs:

- Wisconsin Medicaid.
- BadgerCare Plus.
- SeniorCare.
- Wisconsin Chronic Disease Program (WCDP).

### Required Documentation for New Patients

Upon initial acceptance of a ForwardHealth member as a patient receiving treatment with clotting factor concentrates, pharmacy providers are required to collect and maintain the following information:

- Name.
- ForwardHealth identification number.
- Address and telephone number.
- Birth date.
- Gender.
- Primary language spoken in the home.
- Weight.
- Inhibitor status.
- Date the current prescription was issued by the prescriber.

- Current clotting factor concentrate prescribed.
- Current dose of clotting factor concentrate.
- Prophylactic and as needed dosing instructions.
- Minimum number of as needed doses the prescriber has determined the member should maintain in the home.
- Estimated quantity of clotting factor concentrate the member has at home.
- Usual pattern of clotting factor concentrate utilization (e.g., for a month).
- Prescribing provider.
- Hemophilia Treatment Center (HTC), if applicable.

### **Reporting Incidents to the Hemophilia Treatment Center or Prescriber**

Within one business day of learning about an incident such as a bleed, trauma, planned elective surgery, or any other situation that may indicate that a member needs to follow up with the prescriber, the pharmacy provider is required to report the incident(s) to the prescriber and/or HTC.

### **Clotting Factor Concentrate Dispensing Requirements**

#### ***Delivery of Clotting Factor Concentrate and Supplies***

Shipments from the pharmacy and deliveries to the member of clotting factor concentrate, including overnight deliveries, must use appropriate cold chain management and packaging practices to ensure proper temperature, drug stability, integrity, and efficacy are maintained during shipment. A signature by the member or caregiver is required upon delivery. A caregiver is defined as any family member or nonfamily person who is responsible for providing the member's health care needs. The words "signature on file" are not acceptable to allow delivery to a location that does not have an individual present to physically receive the delivery. The pharmacy provider may not instruct a delivery service to leave a package at a location where an individual is not present to receive the delivery.

### ***Emergency Situations***

Pharmacy providers are required to establish and document processes that ensure patient access to clotting factor concentrates in an emergency situation and to communicate these processes to the member. Emergency processes should be coordinated with the prescriber and/or HTC.

### ***Assay Management***

Prescriptions for clotting factor concentrate must be filled within plus or minus five percent of prescribed assays, unless extenuating circumstances exist and are documented by the pharmacy. Variance in the prescription or target dosage for clotting factor concentrate must not exceed five percent, as measured in aggregate per quarter.

### ***Maintenance of Stock***

Pharmacy providers are required to stock clotting factor concentrate products in assay range levels sufficient to dispense treatment regimens as prescribed for a member and to ensure dispensing within the variance parameters described in the Assay Management section of this *Update*.

### ***Auto Fill***

Pharmacy providers may not auto fill prescriptions for clotting factor concentrate.

### ***Initiation of Dispensing***

Requests for the dispensing of clotting factor concentrate must be initiated by the member or caregiver. Pharmacy providers are required to contact the HTC or prescriber if a refill is due and has not been requested by the member or caregiver. Pharmacy providers may not dispense multiple refills of a clotting factor concentrate at one time.

### ***Filling or Refilling Prescriptions***

Upon contact by a member or caregiver to request an initial fill or refill of clotting factor concentrate, pharmacy providers are required to request the following information from the member or caregiver and maintain the information:

- The amount of clotting factor concentrate that the member currently has on hand.
- Assessment of any unexpected variation from usual patterns of clotting factor concentrate utilization.
- The member's current address and telephone number for delivery of clotting factor concentrate.

In addition, the pharmacy provider is required to confirm the delivery date with the member.

### ***Days' Supply***

Pharmacy providers are required to dispense clotting factor concentrate based on the prescription and the member's current clinical situation such that the member maintains a supply sufficient to meet the member's needs for prophylactic dosing, if applicable, and additional as needed doses for treatment of bleeds necessary based on the prescriber's order(s) and/or the emergency plan for the member.

### ***Prohibition of Billing for Drugs Used During Inpatient Hospital Stays***

Pharmacy providers may not bill ForwardHealth for drugs, including clotting factor concentrate, dispensed to a member or to a hospital for use by the member during an inpatient hospital stay.

### ***Clotting Factor Concentrate Purchasing Records and Reporting Requirements***

When requested by ForwardHealth, pharmacy providers are required to provide detailed copies of purchase invoices that document clotting factor concentrate inventory acquired and dispensed.

### **Product Recalls**

#### ***Product in Stock***

Pharmacy providers are required to immediately remove and quarantine any stock of recalled clotting factor concentrate, equipment, or supplies on the pharmacy premises.

#### ***Items Previously Dispensed***

Pharmacy providers are required to notify members of a recall of clotting factor concentrate, equipment, or supplies within 24 hours of receiving notice of the recall. Pharmacy providers are required to retrieve and quarantine any recalled clotting factor concentrates, equipment, or supplies dispensed to the member within seven calendar days of notifying the member.

#### ***Prescriber Notification***

Pharmacy providers are required to inform the prescriber of a clotting factor concentrate recall within 24 hours of receiving notice of the recall. In addition, pharmacy providers are required to inform the prescriber of the member's available supply of usable clotting factor concentrate and may obtain a prescription for an alternative product, as appropriate.

#### ***National Patient Notification System***

Pharmacy 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. For additional information about the National Patient Notification System, providers may refer to the National Patient Notification System Web site at [www.patientnotificationssystem.org/](http://www.patientnotificationssystem.org/).

### **Adverse Effects**

#### ***Member Education Related to Adverse Effects***

Pharmacy providers are required to counsel the member, family, and/or caregiver in accordance with the Omnibus

Budget Reconciliation Act of 1990 (OBRA '90) to encourage appropriate medication use, promote realistic therapy expectations, help members manage or minimize adverse effects (including those that can be related to inhibitors), and encourage adherence.

## **Contact and Communication with Members**

### ***Communication Related to Clotting Factor Concentrate Brands***

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

### ***Communication Related to Elective Procedures***

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

### ***Gift Ban***

Pharmacy providers are prohibited from providing gifts or facilitating gift giving from another entity to a member, member's family, and/or caregiver. Gifts are any gratuity, discount, entertainment, travel, transportation, hospitality, loan, forbearance, use of pharmacy provider-owned vehicle, or other tangible or intangible item having more than a nominal monetary value.

## **Services Must Meet Program Requirements**

Pharmacy providers who receive Medicaid or WCDP 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 ForwardHealth upon request. ForwardHealth may deny or recoup payment for services that fail to meet program requirements.

## **Information Regarding Managed Care Organizations**

This *Update* contains fee-for-service policy for members enrolled in Medicaid and BadgerCare Plus who receive pharmacy services on a fee-for-service basis only. Pharmacy services for Medicaid members enrolled in the Program of All-Inclusive Care for the Elderly (PACE) and the Family Care Partnership are provided by the member's managed care organization (MCO). Members who are enrolled in the WCDP only are not enrolled in MCOs.

The *ForwardHealth Update* is the first source of program policy and billing information for providers.

Wisconsin Medicaid, BadgerCare Plus, SeniorCare, and Wisconsin Chronic Disease Program are administered by the Division of Health Care Access and Accountability, Wisconsin Department of Health Services (DHS). The Wisconsin AIDS Drug Assistance Program and the Wisconsin Well Woman Program are administered by the Division of Public Health, Wisconsin DHS.

For questions, call Provider Services at (800) 947-9627 or visit our Web site at [www.forwardhealth.wi.gov/](http://www.forwardhealth.wi.gov/).

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