STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

Office of Systems, Operations & Pharmacy
Medical Care Programs

Charles E. Lehman
Executive Director

Maryland Medical Assistance Program
General Provider Transmittal No. 70
October 27, 2008

TO: Specialty Pharmacies
Hematologists
Hemophilia Treatment Centers

FROM: Charles E. Lehman, Executive Director
Office of Systems, Operations & Pharmacy

NOTE: Please ensure that appropriate staff members in your organization are informed of the contents of this transmittal.

SUBJECT: Clarification of Clotting Factors Prior-Authorization Requirements

****

This transmittal serves to clarify the Program's prior-authorization requirements for the clotting factors and for immune tolerance induction therapy used in the management of Hemophilia A with inhibitors.

Included in this transmittal are guidelines that are established by the Pharmacy Program to ensure proper utilization of the clotting factors used in the Maryland Medicaid fee-for-service hemophiliac population. The revised forms associated with requests for prior-authorization for payment of the clotting factors are attached.

REVISED GUIDELINES FOR THE PRESCRIBING AND DISPENSING OF CLOTTING FACTORS, EFFECTIVE DECEMBER 1, 2008

1. **On-Demand Treatment**

   a. On-demand use of clotting factors for the treatment of bleeds as they occur does not require prior-authorization by the State prior to shipment by the specialty pharmacy provider as any bleed requires immediate care. However, all factor claims are subject to post-payment review and manual pricing to ensure that the units are billed and paid correctly and that the therapy and dosing regimen are used appropriately for an FDA-approved indication or a medically-accepted indication. Providers may ship the factor based on a valid prescriber's order. Providers should first verify recipient's eligibility before shipping the drug and submit the proper invoice along with the required documents to the State (Refer to Pharmacy Transmittal No. 173 dated Mar 1, 2004).

b. To avoid unnecessary drug wastage due to the short shelf-life of clotting factors, the requested antihemophilic drug should be dispensed in sufficient quantities to take care of the immediate bleeds. After the acute bleeding episode, the Program will authorize no more than 6 doses to be kept on hand for "prn" use for future suspected bleeds. Sending more than 6 doses per shipment may result in the drug expiring before it gets used.

c. With frequent reports of bleeds necessitating frequent early refills by the recipient, the dispensing pharmacist should contact the clinician to discuss issues related to compliance, under-dosing, or drug storage problems (i.e. factors left unrefrigerated or at inadequate refrigerator temperature, etc.). All factor infusions should be documented on the Recipient-Kept Clotting Factors Administration Record (or Infusion Log). This document is now mandatory. If needed, the recipient's REM case manager will be able to assist the recipient or caregiver in completing the infusion log for the family. A copy of this document should be kept by the dispensing pharmacist and submitted to the Program with each clotting factor claim along with other paper work requirements.

2. Prophylaxis Treatment

a. The Program will authorize prophylaxis dosing if the recipient's clotting factor level is equal to or below 2% of normal. A copy of the recipient's lab test showing factor levels must be faxed to the State before initiation of factor prophylaxis.

b. A month supply of the prophylactic dosing regimen is allowed per claim, based solely on the units prescribed for the standard dosing schedule, without accounting for the "prn" doses. This is done to avoid accumulation of drugs that have short expiration dates. Early refills due to unforeseen or unusual bleeds during the month can be dispensed by the pharmacist without the need to call for prior-authorization as long as the extra "prn" doses used for unusual bleeds are documented on the Recipient-Kept Clotting Factors Administration Record.

3. Request of Clotting Factors for Vacation, Surgery, or Anticipation of Loss of Coverage

a. A large supply of clotting factors requested in anticipation of future loss of insurance coverage or long vacations will not be authorized. Because clotting factors can be shipped overnight to almost any place in the US, there is no reason to send more than a month supply at a time. The Program will deny all claims submitted for more than a month supply.

b. Large supplies of factors necessitated by scheduled surgeries or actual bleeds do not require prior-authorization. Documentation of scheduled surgeries and/or actual bleeds should be made on the recipient's infusion log.

4. Immune Tolerance Induction Therapy:

a. For recipients with hemophilia with inhibitors, initiation of immune tolerance induction therapy (ITIT) at any dosing regimens must be initially prior-authorized by the State prior to shipping the factors. Based on a careful evaluation of the scientific literature on ITIT which includes the preliminary findings of the on-going International Randomized Immune Tolerance Study (www.itistudy.com), the Program will approve up to the equivalent of 50u/kg/day used as ITIT dosing regimen. Currently, there is no established standard of care or no established scientific evidence to guide therapeutic decision-making for the treatment of hemophilia A with inhibitors to hemophilic factor.

b. For recipients approved for ITIT, a copy of lab tests documenting the pertinent inhibitor levels and factor levels must be submitted to the Program when available to justify starting the recipient on ITIT and maintaining them on long-term ITIT. It is expected that ITIT will be stopped and the recipient switched to the standard antihemophilic prophylaxis dosing regimen when the inhibitors are eradicated.

c. Failure to obtain prior-authorization from the State or comply with the Program's guidelines for anti-hemophilic therapy may result in denial of payment even when these services were rendered in good faith.

Questions concerning this memorandum should be addressed to the Clinical Pharmacist of DHMH at 410-767- 1455.

Attachments (3)

INSTRUCTIONS FOR COMPLETING THE CLOTTING FACTOR STANDARD INVOICE

This form is mandatory and must be filled out by the dispensing pharmacist when dispensing clotting factors. Providers may create a template of this form for computer generated claims. Important points to note:

- The original signatures of the dispensing pharmacist and the drug purchasing agent or representative of the pharmacy are mandatory on all clotting factor standard invoices.
- Each Rx is valid for up to 365 days of therapy. Effective December 1, 2008, providers must assign a different Rx# per drug NDC dispensed. All vials from different lot numbers but corresponding to the same NDC must be combined and billed under the same Rx#. To avoid confusion and claim rejections, and because the quantity billed for each fill is different from one month to another, it is recommended that providers do not use refill numbers on clotting factor claims. Make all claims the original prescriptions. The maximum day supply allowed per claim is 34. Claim submitted for greater than 34 days will be rejected. Use the same Date of Service as the Date Written.
- The original Rx must be filled within 120 days of the date written. It may be faxed directly by the prescriber to the pharmacy but may not be called in. Any change affecting the drug used, dosage, and dosage frequency requires a new signed prescription. Orders written "as directed" are not acceptable and claims will be returned for clarification of dosage. Orders written "As needed" must have an approximate dosage frequency and/or a limit on the number of doses per day or per month.
- The number of units dispensed must reflect the dosage and dosage frequencies prescribed.
- Prophylactic use of clotting factors must be justified based on the severity of disease condition. Initiation and continuation of all immune tolerance induction therapies must be prior-authorized by the State. Pertinent factor levels and factor inhibitor levels with updates on the recipient's bleeding status must be faxed to the Program routinely when the clinical information is available.
- Document any drug adverse effects, drug shortage/surplus, any waste of medication, any unusual bleeding or any compliance issues on the Clotting Factor Administration Record.
- Submission of a copy of the factor purchase invoice, the Recipient-Kept Factor Administration Record, the clotting factor order, the Pharmacist Clotting Factor Dispensing Record, and proof of delivery are mandatory. The recipient, caregiver, and/or case manager must assist the pharmacist with information on actual usage when requesting a refill. All information documented on any forms must be accurate and valid as it is subject to audit by the State.

ON-LINE BILLING INSTRUCTIONS FOR CLOTTING FACTOR AND HIGH-COST DRUG CLAIMS

Bill as one claim per Rx# per drug NDC of the same product. If the product calls for use of various potencies necessitating multiple drug NDCs being dispensed, bill multiple claims, one per drug NDC, per month as called for:

1. Enter Rx number and all required data elements. Submit claim with compound code 0 or 1.
2. Use the actual NDC for factor or high-cost drug. If different lot numbers for the same NDC are dispensed, combine the vials and bill under the same RX #. Create a different Rx# for each clotting factor refill because the quantity dispensed on each refill may not be the same as the quantity on the original Rx due to various assays. Payments will be released based on the units billed per drug NDC.
3. Enter the usual and customary charge (U/C). Claim will deny with NCPDP error code 75, "Prior-Authorization is required", error code M5 "Requires Manual Claim-Forward paper claim to the State", and error code 78, "Cost exceeds maximum- Contact ACS at 1-800-932-3918" However, there is no need to call for PA. The system has been programmed to reject all high cost drug claims for manual pricing and review. Any DUR alerts and claim submission errors must be resolved before the claim is rejected for manual review. Providers are to ship the drug provided that the recipient's therapy is medically necessary and the recipient meets the criteria for clotting factors replacement. Complete the Clotting Factor Standard Invoice and mail to OSOP, PO Box 2158, Baltimore, MD 21203 with the required documents. DO NOT FAX CLAIMS TO THE STATE. Claim will be returned if the required documents are missing. Keep all dispensing records with the original signed prescriptions on file for six years. Payments will be manually released by the State.

Questions concerning completion of this form should be directed to the Maryland Pharmacy Program, Department of Health and Mental Hygiene at 410-767-5701.

c:\ Word\ClottingFactorsStandardInv&BillingInstNov08

MARYLAND MEDICAL ASSISTANCE PHARMACY PROGRAM

CLOTTING FACTORS STANDARD INVOICE

PATIENT CLINICAL/Rx INFORMATION

Phone: 410-767-1455 or 1-800-492-5231 Option 3

Recipient:_____Age____ On Medicare? Yes___No___Other insurance:___

MA # : _____(11 digit #)- Current Body Weight:_____lbs or _____kg

Address: _____Tel.#: (_____)_____-_____

Diagnosis: Hemophilia A__; Hemophilia B__; Hemophilia with inhibitors to Factor(s)___; von Willebrandt ___

List degree of severity based on Factor blood level:_____iu/ml – Test date:_____

___ Severe (plasma Factor levels <0.01 iu/ml or <1% of normal)

___ Moderate (plasma Factor levels between 0.01-0.05 iu/ml or 1-5% of normal)

___ Mild (plasma Factor levels between 0.05 and 0.4 iu/ml or 5-40% of normal)

Name of clotting factor:_____Is Recipient enrolled in a clinical trial? ☐ Yes; ☐ No

AHF Factor VIII___Factor IX conc.___Anti-inhibitor Coagulant Complex___Other_____

Dose range:_____AHF IU/dose based on:_____AHF/kg of BW

Dosage frequency: _____(Ut dict not acceptable-Prn orders must have an approximate

% correction factor desired:_____% dosage frequency or specified max daily doses);

Most recent Factor Level:_____Date:_____Factor Inhibitor Level:_____Date:___

Prophylactic use: Yes___ No___ No more than 6 doses per claim to be kept for "On-demand or "prn use"

All initiation and continuation of immune tolerance induction therapies must be prior-authorized by the State.

MANDATORY PRICING INFORMATION

Complete and sign the following mandatory section for clotting factor:

Direct price charged by manufacturer for factor/high-cost drug: $_____per unit.

All discounts, chargebacks, rebates received: $_____per unit.

Actual acquisition cost paid for the factor: $_____per unit.

I attest that the above pricing information is accurate. Supporting documentation as to the pricing information is available for State audits.

_____ _____ (_____) _____-_____

Purchasing Representative's original signature Date Phone #

Name of Purchasing Representative: _____

CLAIM INFORMATION

Service Provider # :_____ Tel # (_____)_____-_____Fax# (_____)_____-_____

Provider NPI #: _____Pharmacy Name:_____

Date of Service: _____Date Written:_____(If possible, do not use refills on clotting factor Rx)

Days Supply:_____days- **Use a separate Rx# per drug NDC for the same clotting factor Rx** which is valid for a year.

Rx#:_____NDC_____ Units/vial*_____#vials:____Quantity:_____

Rx#:_____NDC_____ Units/vial*_____#vials:____Quantity::_____

Rx#_____NDC_____ Units/vial*_____#vials:____Quantity:_____

Rx#_____NDC_____ Units/vial*_____#vials:____Quantity:_____

*** Vials with the same NDC although from different lot numbers must be combined and billed under the same Rx #.**

I certify that the units dispensed are accurate and that I will be monitoring the recipient's therapy.

_____ _____ (_____) _____- _____

Dispensing Pharmacist's signature Date Phone #

Please attach copies of the following documents to each Clotting Factor and High-Cost Drug Standard Invoice and send to:

DHMH - Office of Operations, Systems and Pharmacy, PO Box 2158 Baltimore, MD 21201:

- ☐ **Mandatory Pharmacist Clotting Factor Dispensing Record**
- ☐ **Mandatory Recipient-Kept Factors Administration Record (Infusion Log).**
- ☐ **Mandatory clotting factor prescription order.**
- ☐ **Mandatory proof of delivery.**
- ☐ **Mandatory copy of purchase invoice showing direct cost paid for the factor.**

FOR INTERNAL USE ONLY-

c:\.Word\ClottingFactorsStandardInvNov08

Approved:$_____Date:_____/_____/_____

Rejected_____ Returned_____ Date:_____/_____/_____

Maryland Medicaid Pharmacy Programs
PHARMACIST CLOTTING FACTOR DISPENSING RECORD

A six-month clotting factor dispensing record and a copy of the previous month's Recipient-Kept Clotting Factors Administration Record must accompany each factor invoice that is submitted to the Program. Vial potencies and lot numbers must be documented on this sheet. The balance of units on hand must be given by the Recipient or Caregiver to the pharmacist when placing a new order.

Recipient:_____MA#:_____Phone# (____)_____-_____
Address: _____
Physician:_____Phone# (____)_____-_____Fax#(_____)_____-_____
Address:_____
Case Manager:_____Phone# (_____)_____-_____Fax# (____)_____-____
Clotting Factor: _____

Date of Service, starting with most recent	Total Units Dispensed by Pharmacy*	# of Vials/ Assay Potencies/ Lot numbers	Total Units Infused Prior to New Shipment	Actual Units On Hand as Reported by Recipient	Order Changes/Unusual Bleeds- Specify location where drug is infused if other than home.

* No more than 6 doses of drug should be kept on-hand at any time for recipient's on-demand use . Emergency supplies are automatically authorized for active bleeds.

I certify that all data submitted are accurate and that I will be monitoring the recipient's proper utilization of the clotting factors. Supporting documentation available for State audits.

Pharmacist's Original Signature: _____ Date:_____
Pharmacist Name:_____
C:\MS Word\FactorRPhClottingFactorDispensingRecordNov08

Maryland Medicaid Pharmacy Programs

RECIPIENT-KEPT CLOTTING FACTORS ADMINISTRATION RECORD

Phone: 800-492-5231 or 410-767-5701- Fax: 410-333-5398

PO Box 2158 Baltimore, MD 21201

Recipient:______________________ MA#:____________________ Phone# (_____)______-______

Current Address: ____

Physician:______________________ Phone# (___ __)_______-__________ Fax# (_____)_____-______

Patient's Case Manager:__________________ Phone#________________ Fax# (_______)______-______

Date/Time Circle (I) for Infusion or (D) for Delivery	**Units Received** (to be added) or **Units Infused** (to be subtracted) –Specify units per vial and number of vials	**Units On-hand after last dose**- Specify units per vial and number of vials remaining in the refrigerator	Explain any unusual bleed(s) requiring additional doses- **Notify Doctor of such bleed. Specify location where drug is infused if other than home.**
________ I / D	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # vials____	U/vial_______ x # Vials____ U/vial_______ x # Vials____ U/vial_______ x # Vials____	
________ I / D	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	
________ I / D	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	
________ I / D	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	
________ I / D	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	
________ I / D	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	
________ I / D	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # Vials____	
________ I / D	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # vials____	U/vial_______ x # vials____ U/vial_______ x # vials____ U/vial_______ x # vials____	

The balance on-hand given to the pharmacist at the time of the call on _____/_____/_____ is: ________________ U

Original Signature of Recipient or Caregiver's:______________________________ **Date:**_____/_____/_____

Name:_____________________________________ Relationship to the Patient:_____________________

<u>**NOTE**</u>: This form is mandatory and may be duplicated. Recipient or Caregiver must keep a record of Recipient's clotting factor infusions and bleeds for the purpose of monitoring compliance and bleeding patterns. The form should be sent to the specialty pharmacy when an order is placed. The pharmacist should ask for the balance of units on-hand at the time of the order and submit this form to the State along with the required paperwork.