STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Robert L. Ehrlich, Jr., Governor – Michael S. Steele, Lt. Governor – Nelson J. Sabatini, Secretary

Office of Operations & Eligibility
Medical Care Programs

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PT 24-04

MARYLAND MEDICAL ASSISTANCE PROGRAM

Pharmacy Transmittal No. 173

March 1, 2004

Specialty Pharmacies

FROM: Joseph E. Davis, Executive Director
Office of Operations and Eligibility

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

Billing of Hemophilia Clotting Factors

Effective April 1, 2004 the Maryland Medical Assistance Program will require pharmacy providers filling prescriptions for hemophilia clotting factors to submit the following documentation with each prescription claim:

1) Standard Invoice for Clotting Factors and High Cost Drugs (with pricing and patient clinical/Rx information)
2) Copy of prescription order signed by the prescriber
3) Clotting Factor and High Cost Drug Administration Record
4) Copy of invoice showing price paid by pharmacy for factor

Prescriptions submitted without these properly completed documents will be returned by the Program with a request for the missing information. Included with this transmittal are copies of the Standard Invoice for Clotting Factors and High Cost Drugs, the Clotting Factor and High-Cost Drug Administration Record, and detailed billing instructions.

Claims for all factors must be submitted on-line through the Pharmacy Point-of-Sale (POS) system. After submission on-line, the claim will deny with the message that preauthorization is required. The pharmacy must then fax (410-333-5398) or mail the above documents to the Office of Operations and Eligibility, PO Box 2158, Baltimore, MD 21203 for manual review and pricing before the claim can be released for payment. Please refer to the detailed billing instructions included with this transmittal.

Please note that on the Standard Invoice for Clotting Factors and High Cost Drugs there is a boxed section concerning pricing information. This section MUST be completed and signed by an authorized representative of the pharmacy provider knowledgeable about the purchasing procedures of the pharmacy. According to current Program regulations, the Program reimburses pharmacy providers for the cost of the drug at an Estimated Acquisition Cost (EAC) which is the lowest of the average wholesale price (AWP) – 12%, the direct price + 8%, the distributor's price + 8% or the wholesale acquisition cost (WAC) + 8%. Providers normally obtain these products directly from the manufacturer rather than a wholesaler so the direct price paid for these products is applicable in the calculation of EAC. Under conditions for participation, Maryland Medicaid regulations require providers to maintain adequate records and make them available for inspection, upon request, to the Department. To ensure that the Program is paying appropriately, the Program is requiring providers to submit a copy of the invoice indicating the direct price charged by the manufacturer to the pharmacy for these products.

To assist the Department in the review and payment of these products, the Clotting Factor and High Cost Drug Administration Record must be completed and signed by the dispensing pharmacist. The pharmacy is responsible for obtaining the drug administration information from the recipient either through use of a written log maintained by the recipient or caregiver or by verbal communication with the recipient as new factor prescriptions are refilled or as prescriptions are called into the pharmacy. The records must go back six months from the date of service being billed. If the administration log is not currently maintained by the pharmacy, the pharmacy may estimate the administration done prior to the date of this transmittal. The form may be different from the enclosed form but must contain the same information, including the date and quantity of all units dispensed by the pharmacy and the date and quantity of all units administered to the recipient. The Program encourages providers to maintain this information in a computer database so that it can be readily generated for submission with each claim.

Questions concerning this transmittal should be directed to the Division of Pharmacy Services at 410-767-1455.

INSTRUCTIONS FOR COMPLETING CLOTTING FACTOR HIGH COST DRUG STANDARD INVOICE

This form is mandatory and must be filled out by the dispensing pharmacist when dispensing clotting factors or any drug or biological with a Usual & Customary Charge **exceeding $2,500.00**. 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 prescription is valid for up to 365 days of therapy. Providers may assign the same Rx# for subsequent fills even if the quantity sent is a different quantity filled for the original prescription. The maximum day supply allowed per claim is 34. Claim submitted for greater than 34 days will be rejected.
- 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.
- Prophylaxis use of the clotting factor must be justified by the severity of disease condition and documented on the invoice.
- Document any drug adverse effects, drug shortage/surplus, any waste of medication, any unusual bleeding or any compliance issues on the Clotting Factor and High Cost Drug Administration Record.
- Submission of the Clotting Factor and High Cost Drug Administration Record by the pharmacy for reimbursement is mandatory. The recipient, caregiver, and case manager may assist the pharmacist with information on actual usage when requesting a refill. All information documented on the infusion log by the pharmacist must be accurate and valid.

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

Bill as one transaction per claim for the same product dispensed in various potencies per month or as called for:

1. Enter prescription number and all required data elements.
2. Use the actual NDC number of the factor. If the NDCs for different vial potencies are used for the same order, bill on-line only the NDC of one of the potencies for the entire claim. In the near future, providers may be able to bill multiple ingredients in one transaction when the new NCPDP version 5.1 will be fully operational. For other high-cost drugs such as Cerezyme treat each strength as a separate prescription. Total units billed on refills may differ in quantity from the original Rx because of varying drug assays.
4. Enter the compound code 0 or 1 to indicate that claim is not a compound.
5. Enter the usual and customary charge (U/C). The new version 5.1 can now accommodates a U/C charge greater than $9,999.99999 and release payment for the exact dollar amount approved for the entire claim in one transaction.
6. Claim will deny with NCPDP error code 75, "Prior-Authorization is required" with the transmission message, "For Prior-Authorization, call DHMH, 410-767-1693". However, there is no need to call for PA. This is the System's mechanism for rejecting the claim for manual review. Any DUR alerts and claim submission errors must be resolved before the claim is rejected for manual review.
7. Complete the Clotting Factor and High-Cost Drug Standard Invoice and mail to OOE, PO Box 2158, Baltimore, MD 21203 with the required documents. Claim will be returned if required documents are missing, if the drug pricing information is not on file with the State, or if the pharmacist did not sign the invoice. Keep all dispensing records with the original signed prescriptions on file for six years.

Questions concerning completion of this Clotting Factor Standard Invoice should be directed to the Division of Pharmacy Services, Department of Health and Mental Hygiene at 410-767-5701.

Maryland Medicaid Pharmacy Programs
Division of Pharmacy Services
CLOTTING FACTOR AND HIGH-COST DRUG ADMINISTRATION RECORD

Records must be accurately kept by the dispensing pharmacist and are subject to audit.
A 6 month-history of factor infusion is required from date of service billed. Form may be computer-generated if containing the same information.

Recipient:_____MA#:_____Phone# (____)_____ _____
Address: _____
Patient Location: Home___; Hospital:____; Clinic:____; Other:_____
Physician:_____Phone# (____)_____-_____Fax#(_____)_____-_____
Address:_____
Case Manager:_____Phone# (_____)_____-_____Fax# (____)_____.

Date	Name of Clotting Factor/ High-Cost Drug	# of Units Dispensed (+)	# of Units Administered to Recipient (-)	# of Units on Hand (Current Balance) =	Treatment Notes/ Adverse Reactions/ Bleeding Occurrences, etc.

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

_____ _____ (_____)_____ _____
Dispensing Pharmacist's Original Signaure Date Phone #

MARYLAND MEDICAL ASSISTANCE PROGRAM
Division of Pharmacy Services
CLOTTING FACTOR AND HIGH-COST DRUG STANDARD INVOICE
(Incomplete forms will be returned)
Fax to 410-333-5398

PATIENT CLINICAL/Rx INFORMATION

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 8 blood level:_____iu/ml –Test date:_____(required)
___ Severe (plasma FVIII levels <0.01 iu/ml or <1% of normal)
___ Moderate (plasma FVIII levels between 0.01-0.05 iu/ml or 1-5% of normal)
___ Mild (plasma FVIII levels between 0.05 and 0.4 iu/ml or 5-40% of normal)
Factors delivered to: Home:____ Hospital: ____Clinic___Other:_____
Name of factor:_____
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 blood factor 8 level:_____Date:_____
Prophylactic use: Yes___ No___ Prophylaxis use is recommended for patients with severe hemophilia or in patients for whom blood factor levels are below 2% of normal. Explain if deviating from this recommendation:
_____

PRICING INFORMATION

Complete and sign the following mandatory section:

Direct price charged by manufacturer for factor dispensed: $_____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 NABP #: _____Pharmacy Name:_____
Rx #: _____(7 digits); Original Rx_____; Refill #_____
Date of Service (Date dispensed): _____ Date (Rx) Written:_____(within 120 days)
Days Supply:_____days (not exceeding 34d/Rx) Total Quantity (units) billed: _____ 5a.
NDC_____ Lot#_____#units/vial:_____#vials:____ Total Units:_____
NDC_____ Lot#_____#units/via:_____#vials:____ Total Units:_____
NDC_____ Lot# _____#units/vial: _____ #vials:____ Total Units:_____

I certify that the units dispensed are accurate and that I will be monitoring the recipient's proper use of the clotting factors.

_____ _____ (_____) _____-_____
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:
DMHM- Office of Operations and Eligibility, PO Box 2158 Baltimore, MD 21203:

- ❑ **Mandatory Clotting Factor and High-Cost Drug Administration Log**
- ❑ **Mandatory signed antihemophilic drug order. For refills, attach copy of signed original order.**

FOR INTERNAL USE ONLY Amount approved: $_____ Date:_____
Rejected/returned: _____ Date:_____