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
Pharmacy Transmittal No. 192
October 30, 2009

TO: Specialty Pharmacies

FROM: Charles Lehman, Executive Director
Office of Systems, Operations and Pharmacy

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

SUBJECT: Billing of High-Cost Drugs

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This transmittal supercedes Pharmacy Transmittal No. 173, dated Mar 1, 2004 and serves to clarify the billing requirements for specific high-cost drugs. Under Transmittal No. 173 (March 1, 2004), the forms used for processing clotting factors and high-cost drugs were combined. However, due to the different type of clinical, as well as, billing information required for the review of these different types of drugs and clotting factors, the Program has since created separate forms for submitting claims for the clotting factors effective Dec 1, 2008 (see General Provider Transmittal No. 70 dated October 15, 2008).

Effective December 1st, 2009, the Maryland Medicaid Pharmacy Program will require specialty pharmacy providers filling prescriptions for certain high-cost specialty drugs that are purchased directly from the manufacturers or that have a reported direct price (i.e. Orfadin, Adagen, Aldurazyme, Elaprase, Naglazyme, Aralast, Prolastin, Zemaira, Ceredase,Cerezyme, Fabrazyme, etc.) to submit the following documentation with each prescription claim:

1. High-Cost Drug Standard Invoice;
2. Signed prescription order;
3. Proof of delivery;
4. Purchase invoice showing Direct Price after discounts and rebates paid for the high-cost drug; and
5. Pharmacist High-Cost Drug Dispensing Record.

Claims submitted without these properly completed documents will be returned to providers, with subsequent delay in payments.

Claims for the high-cost drugs must be submitted on-line through the Point-of-Sale (POS) system and will deny for manual review and pricing. Although the services had been rendered before billing the State, providers must expect that payments will only be released if the services rendered were medically necessary and adhered to COMAR regulations. The Program may reject any claims upon manual review if:

a. The units billed are not consistent with the prescriber's orders; and
b. If the evidence-based prescribed drug therapy and continuation of long-term drug therapy is not medically necessary and conform to acceptable standards of medical practice.

Off-label uses of medications are covered only if such uses are documented and strongly supported in one of the 3 official compendia, the Micromedex Drugdex, the AHFS Drug Information, and the U.S. Pharmacopeia National Formulary. Pharmacy providers may call the State at 410-767-5701 for instructions on how to process a manual claim. All manual claims must be forwarded with the required documents to the Office of Systems, Operations, and Pharmacy (OSOP), PO Box 2158, Baltimore, MD 21203. Please refer to the detailed billing instructions included in this transmittal.

Reimbursement for the high-cost claim will be made in accordance with COMAR regulations (10.09.03.07 - Payment Procedures). To ensure proper drug reimbursement, the Program requires that providers submit a copy of the actual invoice indicating the direct price charged by the manufacturer to the pharmacy for these products (providers usually obtain these products directly from the manufacturer, sometimes through manufacturers' restricted distribution programs and seldom through a wholesaler).

Under Conditions for Participation (COMAR 10.09.03.03), Maryland Medicaid regulations require providers to maintain adequate prescription records for a minimum of 6 years, to make them available for inspection, upon request, to the Department or its designee, and to include on all prescriptions sufficient information to justify the high-cost drug pharmacy invoice charges.

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) requires that the pharmacist counsel the recipient on the proper use of medications. The dispensing pharmacist must offer to discuss the unique drug therapy regimen (for a Medicaid recipient) when filling prescriptions for them. Such discussions must include matters that are significant (in the professional judgment of the pharmacist) which include, but are not limited to, the following: name and description of the medication, route of administration, dose, dosage form, and duration of drug therapy. OBRA '90 also mandates pharmacists to discuss special directions and precautions for preparation of drugs, administration and use by the patient; common and severe side effects or adverse effects and drug interactions and therapeutic contraindications that may be encountered (including their avoidance and the action required if they occur); techniques for self-monitoring drug therapy; proper storage; refill information; and appropriate action in case of a missed dose.

The dispensing pharmacist must account for all drug holiday periods, all "out-of the country" extended vacation stays or short vacation periods, as well as periods of hospitalizations when the recipients are not administering any high-cost medications and thus may accumulate a large amount of the high-cost medications. Providers must verify recipient's actual drug balance on-hand before shipping a new batch to the recipient. They should not bill theoretically based on predicted need without a request for a refill made by the recipient or his/her caregiver.

Since April 1, 2004, the dispensing pharmacist has been required to complete the Pharmacist High-Cost Drug Dispensing Record with each submitted claim, going back six months from the date the service was last billed. This dispensing record is required to rule out duplicate claims or claims that were submitted out of sequence, after the fact, and months later without actual proof of delivery. Due to frequent company mergers, it is not unusual for the new incoming company to submit outstanding claims on behalf of the exiting company, using past dates of services that do not match with the Pharmacist Dispensing Records. If the Dispensing Pharmacist from the dissolved company is no longer working for the new company, thus making any dispensing verification difficult, the Program will deny any claims that have not been documented by the Actual Dispensing Pharmacist on the Official Pharmacist High-Cost Drug Dispensing Record. Under no circumstances, should providers bill the Program for a shipment of a high-cost drug on a system-programmed "auto-mode", i.e. automatically without the approval or the actual refill request made by the recipient or recipient's designated caregiver.

If the drug is shipped to the recipient's home address, a signature from the recipient or caregiver is required. If a signature cannot be obtained, a shipping tracking number may be used as proof of delivery. The Program encourages providers to send to the State a copy of the packing slip, especially when there is discrepancy raised about the quantity sent and date of service billed. Providers must be consistent at using only one date as the date of service. Often times, providers may submit duplicate claims inadvertently by billing both for the fill date and the ship date (usually the ship date is the day following the fill date). Thus, when providers attempt to reconcile their remittance advices, they are looking for payments for the duplicate claims because of the different submitted date of service, which creates unnecessary work and leads to chasing non-existing claims.

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

MARYLAND MEDICAID PHARMACY PROGRAM
HIGH-COST DRUG 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.#: (_____)_____-_____
Indication for prescribed Drug: _____
Required drug levels or biochemical parameters- when applicable to specific drugs:
Specify lab test:_____-Result: _____Date: _____/_____/_____
Normal Range: _____
High-Cost Drug: _____
Dosage prescribed:_____

MANDATORY PRICING INFORMATION

Complete and sign the following mandatory section for the high cost drug:

Direct price charged by manufacturer for high-cost drug: $_____ per unit.
All discounts, chargebacks, rebates received: $_____per unit.
Actual acquisition cost paid for the high-cost drug: $ _____ 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:_____/_____/_____
Days Supply:_____days- Use a separate Rx# per drug NDC.

Rx#: _____NDC#_____Drug/Strength_____Quantity:_____
Rx#: _____NDC#_____Drug/Strength_____Quantity::_____

I certify that the units and date of service dispensed are accurate and that I will be monitoring the recipient's therapy. All claims submitted on auto-mode for testing purpose must be reversed before the actual claims are submitted for payment. All claims for invalid service dates are considered fraudulent and subject to audits.

_____ _____ (_____) _____-_____
Dispensing Pharmacist's signature Date Phone #

Please attach copies of the following documents to each High-Cost Drug Standard Invoice and send to:
DHMH- Office of Systems, Operations and Pharmacy, PO Box 2158 Baltimore, MD 21203:

- ☐ **Mandatory Pharmacist High-Cost Drug Dispensing Record**
- ☐ **Mandatory copy of prescription order.**
- ☐ **Mandatory proof of delivery.**
- ☐ **Mandatory copy of purchase invoice showing direct cost paid for the high-cost drug**

FOR INTERNAL USE ONLY- Approved:$_____Date:_____/_____/_____
Rejected_____ Returned_____ Date:_____/_____/_____
Comments:_____

MARYLAND MEDICAID PHARMACY PROGRAM
INSTRUCTIONS FOR COMPLETING THE HIGH-COST DRUG STANDARD INVOICE

This form is mandatory for the specific drugs on the list of "Drugs Requiring Manual Review and Pricing" (See Table I). Providers may create a template of this form for computer-generated claims. Important points to note:

- The original signatures of the Dispensing Pharmacist and Purchasing Agent/Sales Manager are mandatory.
- Each Rx is valid for up to 365 days of therapy with a max of 11 refills per Rx, max 34-day supply per claim. Providers must bill one Rx # or one claim per drug NDC dispensed. For ex., a prescription for Cerezyme 1000U every 14 days may be filled with vials from 2 different strengths (200U and 400U) and should be billed as 2 separate claims. Billers must be aware of the proper unit of measurement in order to bill correctly. For ex., with Cerezyme, the unit for the powder vial is "each" for each vial. So, the quantity billed should be the # of vials and not the # of units. The units from 2 vials of different potencies cannot be combined and billed under one claim. The vials have different NDCs and are sent to the home in the unreconstituted form.
- High-cost drugs that are prepared by the home intravenous infusion pharmacist may not necessarily need manual pricing when they are not listed on Table I below. In this case, the paperwork does not need to be sent to the State. The pharmacist should call ACS for prior-auth for the "Cost Exceeds Max" exception code if the cost exceeds $2,500. If 2 different package sizes (with 2 different NDCs) of the same product are dispensed, bill as separate claims for the 2 vials if dispensed as separate Rxs (i.e. Vivaglobin 6% in package sizes of 2ml and 20ml). The units of measurement for the unreconstituted vials are "ml' for the liquid (i.e. Vivaglobin, Adagen, etc.) and "each" for the powder (i.e. Cerezyme). For the active drugs, always bill the units of the unreconstituted vials. If the pharmacist should actually compound the drug by mixing the content of 2 different vial package sizes, then the 2 different vial NDCs should be billed as a compound, with compound code 2, under one claim, using the multi-line ingredient system functionality.
- The number of units billed must always reflect the dosage prescribed. A copy of the original Rx must accompany each invoice. A diagnosis should be documented on the invoice to rule out undocumented off-label use. Any changes affecting the drug used, dosage, and dosage frequency require a new signed Rx. Orders written "as directed" are not acceptable. Orders written "as needed" must have an approximate dosage frequency and/or a limit on the number of doses per day or per month. When required, a body weight must be documented to assist the pharmacist or the reviewer in determining proper dosage.
- Initiation of therapy for certain restricted high-cost drugs requires clinical prior-authorization to ensure appropriate prescribing of the medication besides service prior-authorization by the State to ensure proper billing by providers and proper drug utilization by the recipient. The Pre-Authorization for High-Cost Drugs - Initiation of Therapy form must be completed by the prescriber and submitted to the Program for review of medical necessity. A copy of the patient's medical history must accompany the prior-authorization request. Depending on the therapy, continuation of therapy may require clinical reassessment of patient compliance, drug response, monitoring of drug levels and adverse effects.
- Certain drugs require close monitoring of specific drug levels or certain biochemical markers due to associated drug side-effects and high toxicity, as recommended or mandated by FDA. Such clinical information should be documented on the invoice and faxed routinely to the Program when the information is required to justify continuation of therapy and ensure patient safety while on the therapy.
- Any drug adverse effects, drug surplus due to missed doses, any wastage of expired medication, or any non-compliance issues must be documented on the Pharmacist High-Cost Drug Dispensing Record to justify the early or late refills.
- Automatic refills are not permitted as they may result in unnecessary drug accumulation and wastage. Providers should not set refills on "auto-mode" or program test claims to adjudicate on-line (if cost <$2,500) even if they are capable of reversing the test claims when the actual claims are submitted. Some non-manual high cost drug claims (that do not require manual pricing) are for 2 different vial strengths, with one adjudicating because of the cost being<$2,500.00 and the second vial with cost>$2,500. Providers still need to call for prior-auth for the therapy involving both drug strengths, even though one drug strength had paid on-line. If the therapy quantity was billed or prescribed inappropriately, the entire therapy will be denied. Any claims that paid improperly will be subject to recovery by the Program. The recipient or caregiver must actually call the Pharmacy to request a refill. Early refills of a high-cost drug must be justified and documented on the Pharmacist High-Cost Drug Dispensing Record with valid reasons for the early refill request.

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

1. Enter Rx number and all required data elements. Use the actual single NDC for the high-cost drug. For an injectable drug, bill one claim (one Rx) per NDC if the vials are sent in the unreconstituted form to the recipient's home. May bill for the diluents used for reconstitution and dilution as separate claims if these are sent separately to the recipient's home. Submit claim with compound code 0 or 1 (non-compound).
2. If the drug should be compounded for the recipient (i.e. Aldurazyme), involving use of compounding supplies and diluents, bill only the active drug under the Pharmacy Program, as a single-line ingredient with compound code 1, using one Rx#. Bill the diluents and supplies under DME/DMS, using the proper HCPC codes. For recipients with no DME/DMS coverage benefits, bill the whole therapy as manual claims under the Pharmacy Program in order to get reimbursed for the supplies.
3. If there is a change in the dosage or dosage frequency, resulting in a different quantity being dispensed, a new prescription must be created and the claim submitted under a new Rx#.
4. The high-cost drug claim must be submitted on-line first for a denial. 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 with the generic message, "Cost exceeds maximum- Contact ACS at 1-800-932-3918". There is no need to call ACS if the claim is a manual claim requiring manual review. . Any DUR alerts and claim submission errors must be resolved. If a long-term clinical prior-authorization (PA) has been issued by the State, providers may go ahead and ship the drug in the correct amount and subsequently forward the paper work to the State for claim review, manual pricing and payment release. For drugs that require monitoring of lab data because of FDA-identified safety issues, providers should fax to the State the required documentation prior to shipping the drug to confirm approval of continuation of drug therapy based on the new lab results.
5. Complete the High-Cost Drug Standard Invoice and mail to **OSOP, PO Box 2158, Baltimore, MD 21203** along with all required documents, the Pharmacist High-Cost Drug Dispensing Record, a copy of the prescriber's order and proof of delivery - DO NOT FAX BATCHES OF MANUAL CLAIMS TO THE STATE.
6. Claim will be returned if the required documents are missing. Keep all dispensing and prescription records on file for six years. Payments will be manually priced and 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.

TABLE I. DRUGS REQUIRING MANUAL REVIEW AND PRICING*

Adagen	
Aldurazyme, Elaprase, Naglazyme	**Orfadin**
Aralast, Prolastin, and Zemaira	
Ceredase and Cerezyme	
Fabrazyme	

* This list is not inclusive. Newer high-cost drugs may be added to this list at a later date.

MARYLAND MEDICAID PHARMACY PROGRAM
PHARMACIST HIGH-COST DRUG DISPENSING RECORD

A six-month high-cost drug dispensing record must accompany each factor invoice that is submitted to the Program. Drug strength/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# (____)_____-____

Date of Service	**Drug/Strength**	**Lot Number**	**Quantity Dispensed**	**Quantity On- Hand as reported by Recipient**	**Side-effects & Drug levels or bio-chemical markers required for drug monitoring.**

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

Pharmacist's Original Signature: _____Date:_____/_____/_____
Pharmacist Name:_____

MARYLAND MEDICAID PHARMACY PROGRAM
PREAUTHORIZATION FOR HIGH-COST DRUGS
INITIATION OF THERAPY

Incomplete forms will be returned- **410-767-1455 or 1-800-492-5231 Option 3** **Fax form to: 410-333-5398**

Section I. Patient Information

Patient location: ____ Home ____ Hospital___ Clinic___Office Date of Birth:_____/_____/____
Patient Name:_____ Phone #: (_____)_____-_____
Address: _____
MA ID#:_____**A copy of Patient Medical History should accompany this request.**

Section II- Drug is used for an FDA-approved indication

Name of Drug/Strength: _____Dosage frequency:_____
Is this dosage within the FDA-recommended range? ☐ Yes ☐ No – If no, explain why:_____
_____
Indications: (Use ICD-9 with short description):_____
_____
Provide results of pertinent lab tests or values confirming above diagnoses:
_____
_____
Provide justification for selecting this high-cost drug over other less expensive yet equally effective therapeutic alternatives: _____

Section III- Drug is used off-label

Drug Name/Strength: _____Dosage frequency:_____
Is this dosage within the FDA-recommended dosage range for the approved use? ☐ Yes ☐ No- If no, explain why:
_____
List off-label indications: _____
List references supporting off-label use:_____
Drugdex Recommendation Rating:_____
Reason for drug selection:_____
_____
Prior-therapies: (Use additional blank paper if more space is needed)
Drug:_____Period used: Fr_____/____/_____. Did drug fail? ☐ Yes ☐ No
Drug:_____Period used: Fr:_____/____/_____. Did drug fail? ☐ Yes ☐ No
List other FDA-approved alternatives that could be considered for this patient but not used:
Drug: _____ Reason for not choosing this drug: _____
Drug: _____ Reason for not choosing this drug:_____
Note: Off-label use or use of this drug at dosages other than recommended by FDA may be approved if medically necessary, safe, appropriate, and documented in and supported by one of the three official compendia (the AHFS Drug Information, the Micromedex Drugdex, and the US Pharmacopeia).
Is drug used as part of a clinical study or trial? ☐ No ☐ Yes- If yes, specify sponsoring organization/drug manufacturer
Specify purpose of study: _____

I certify that the information provided is accurate. Supporting documentation kept in the patient's medical record is available for State audits.

_____, M.D. Prescriber's Name: _____ Date: ____/___/___
(Prescriber's signature). Tel# (_____) – _____-_____Fax# (_____) - _____ - _____
License #: _____DEA #:_____ Specialty : _____
Address:_____
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MARYLAND MEDICAID PHARMACY PROGRAM
PREAUTHORIZATION FOR HIGH-COST DRUGS
CONTINUATION OF THERAPY

Incomplete forms will be returned- 410-767-1455 or 1-800-492-5231 Option 3 Fax form to: 410-333-5398

Section I- Patient Information

Patient location: ____ Home; ____ Hospital___ Clinic___Office Date of birth:_____/_____/____
Patient Name:_____ Phone #: (_____)_____-_____
Address: _____
MA ID#:_____

Section II- Rx Information

Drug/Strength: _____Dosage frequency:_____
Date of Initial therapy: ____/_____/_____

Section III- Continuation of Therapy

Provide any applicable monitoring parameters and lab tests results to support safe continuation of therapy for this drug in this patient:
Drug level: _____Date measured:_____
Lab tests: Specify type (i.e. liver function test, blood test, etc.:
_____Test Date: _____ ☐ Results normal ☐ Results abnormal
_____ Test Date: _____ ☐ Results normal ☐ Results abnormal
_____ Test Date: _____ ☐ Results normal ☐ Results abnormal
_____ Test Date: _____ ☐ Results normal ☐ Results abnormal
_____ Test Date: _____ ☐ Results normal ☐ Results abnormal
Patient's clinical response to the drug has been: ☐ positive ☐ negative
Is medication approved for long-term use? ☐ Yes ☐ No
If drug is not indicated for long-term use, does the medical literature or official compendia support safe chronic use of the drug? ☐ Yes ☐ No
Action taken:
☐ Continue same therapy for: ___ months
☐ Discontinue therapy due to: ___ side-effects/adverse events
___ therapeutic failure or lack of response
___ Other reasons: _____
☐ Replace drug with_____ ☐ Add following agent to existing therapy_____
_____
Based on an evaluation of patient's clinical conditions, lab test results and clinical data, is continuation of this high-cost therapy justified in terms of long-term safety and efficacy in this patient? ☐ Yes ☐ No
Comment on the drug's efficacy, adverse effects, or any compliance issues: _____
_____
_____

I certify that I have evaluated and monitored patient's lab test results & clinical data to ensure safe use of this drug in this patient. Supporting documentation kept in the patient's medical records is available for State audits.

_____, M.D. Prescriber's name: _____
(Prescriber's signature). Date: _____/_____/_____
Tel# (_____) – _____-_____ Fax# (_____) - _____ - _____
License #: _____DEA #:_____ Specialty : _____
Address:_____
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