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::_____
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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:_____

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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.

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ON-LINE BILLING INSTRUCTIONS FOR 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 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.

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