

# PROVIDER BULLETIN

No. 11-51

DATE: September 20, 2011

TO: Physicians participating in the Nebraska Medicaid Program

FROM: Vivianne M. Chaumont, Director   
Division of Medicaid & Long-Term Care

BY: Jeanne Garvin, M.D., Medicaid Medical Director  
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RE: Medicaid Prior Authorization: Enzyme-Replacement Therapy (ERT) for Lysosomal Storage Disorders

***This provider bulletin replaces Provider Bulletin No. 08-01 (January 18, 2008).***

**Please share this information with professional, clinical, administrative, and billing staff.**

Lysosomal storage disorders include any one of several inherited metabolic disorders. A number of distinct clinical types and numerous subtypes have been identified. These include, but are not limited to, Hurler Syndrome, Scheie Syndrome, Hurler-Scheie Syndrome, Hunter Syndrome, Maroteaux-Lamy Syndrome, Fabry Disease, and Gaucher Disease. Unique enzyme-replacement therapy has been developed for a number of these metabolic disorders, often designated as orphan-drug status by the Food and Drug Administration (FDA).

Medicaid requires prior authorization of all enzyme-replacement therapy for lysosomal storage disorders. This includes, but is not limited to, the follow enzyme-replacement drugs:

## **THERAPY**

- Laronidase (Aldurazyme)
- Idursulfase (Elaprase)
- Agalsidase Beta (Fabrazyme)
- Alglucerase (Ceredase)
- Imiglucerase (Cerezyme)
- Galsulfase (Naglazyme)

## **FOR TREATMENT OF...**

Hurler Syndrome (MPS I), Hurler-Scheie Syndrome, and Scheie Syndrome with moderate to severe symptoms

Hunter syndrome (MPS II)

Fabry disease

Gaucher disease Type I

Gaucher disease Type I

Maroteaux-Lamy Syndrome (MPS VI)

## **MEDICAID COVERAGE OF ENZYME-REPLACEMENT DRUGS**

- **Prior Authorization (PA):** Enzyme-replacement medications for lysosomal storage disorders will be covered by prior authorization only. This applies to current medications available and any future enzyme-replacement drugs that might become FDA approved. (See below for PA process.)

- **Metabolic Specialist Evaluation:** Prior authorization must be requested by the metabolic specialist who evaluated the client and recommended the treatment plan.
- **Medical Necessity:** Coverage of individual drugs must be medically necessary; coverage will be for the specific diagnoses as listed above. All other indications are considered experimental and investigational and will not be covered.
- **Place of Service:** Because of significant side effects, drugs will initially only be covered in physician's office or hospital outpatient or inpatient setting; ongoing administration may be covered as a home health service if the metabolic specialist okays this place of service and if separate prior authorization of home health services is obtained per Medicaid requirements.

### **MEDICAID PRIOR AUTHORIZATION PROCESS**

- **Metabolic Specialist Evaluation:** Documentation from the evaluating/treating metabolic specialist\* to establish the diagnosis and treatment plan must be submitted and is to include the following:
  - *Subjective findings* (symptoms, family history)
  - *Objective findings* (exams, lab results) **Please attach copies of medical reports and tests.**
    - Medical history (including presenting and current symptoms)
    - Physical examination
    - Enzyme levels or other laboratory testing
    - Genetic Testing (e.g., DNA mutation analysis)
  - *Complications of disorder* (e.g. kidney failure, bony changes)
  - *Recommended Plan of Care* Treatment plan must include parameters by which effectiveness of medication will be monitored.
  - *Medical professional and/or hospital facility which will administer infusion therapy and coordinate care with the metabolic specialist for the treatment plan.*
- **Initial Authorization:** Initial drug therapy authorization will be for 6 months.
- **Follow up Authorizations:** To be submitted by the metabolic specialist who is overseeing the care plan and reevaluating the patient. All prior authorizations for Medicaid reimbursement for ERT must be renewed by the end date indicated on the previous authorization to ensure reimbursement for future administration of the drug. Renewal requests must document follow-up information to note any significant changes in physical findings, laboratory parameters, and symptoms; and documentation must show client's compliance with at least 90% of treatment plan. In addition, evaluation of the effectiveness of the medication must be documented.
- **Prior Authorization Form (suggested):** Attached is a prior authorization form for your use. Prior authorization requests cannot be considered without the attached copies of medical records to document requirements listed above for both initial and subsequent authorizations.

*\* Form letters provided by drug manufacturers or drug order forms will not be accepted methods of requesting prior authorization. The Department also is unable to accept prior authorization requests from third party entities that provide prior authorization services.*

### **MEDICAID BILLING AND REIMBURSEMENT**

- **Claims: All claims must include the HCPCS code and NDC of the drug administered.**
  - **Practitioner Claims** will be reimbursed at invoice cost for the drug; other appropriate codes may be billed in addition to the drug when given in the practitioner's office or clinic. Services must be billed in a manner compliant with the National Correct Coding Initiative (NCCI).
  - **Hospital Outpatient Claims, Home Health Claims, and Pharmacy Claims** will be paid per the payment methodology in place at the time of the service. Services must be billed in a manner compliant with the National Correct Coding Initiative (NCCI).

**NE MEDICAID ENZYME-REPLACEMENT THERAPY FOR LYOSOMOL STORAGE DISORDER(S)**

PRIOR AUTHORIZATION FORM

Patient Name \_\_\_\_\_

Medicaid ID # \_\_\_\_\_ Date of Birth \_\_\_\_\_

Ordering Physician (please print) \_\_\_\_\_ Specialty \_\_\_\_\_

Please indicate:  Initial request or  Subsequent request

Diagnosis: \_\_\_\_\_ Date of Diagnosis \_\_\_\_\_

Diagnosis established by the following: **(please attach medical record test results)**

Lab tests  Genetic tests

Medical Assessment: Weight \_\_\_\_\_ kg Height \_\_\_\_\_ inches

Symptoms and clinical findings consistent with diagnosis-list all that apply. For subsequent requests, indicate current symptoms and improvements since the last prior authorization: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

How are you evaluating the effectiveness? \_\_\_\_\_

Has the medication been effective? \_\_\_\_\_

Treatment/Plan of Care Recommendations:

Drug: \_\_\_\_\_ NDC \_\_\_\_\_ HCPCS code \_\_\_\_\_

Frequency of administration \_\_\_\_\_ Anticipated therapy start date \_\_\_\_\_

Anticipated follow-up evaluation: \_\_\_\_\_ weeks \_\_\_\_\_ months

Facility/Physician administering drug if different from requesting metabolic specialist \_\_\_\_\_

Any additional treatment information: \_\_\_\_\_

Physician Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Physician Address: \_\_\_\_\_

Fax #: \_\_\_\_\_ Phone # \_\_\_\_\_

Submit this form and attached medical records to: **Program Specialist – Physician Services** by:  
**Fax** with your office coversheet at (402)471-9092 or **Mail** to P.O. Box 95026, Lincoln, NE 68509

**DO NOT WRITE BELOW THIS LINE – FOR MEDICAID RESPONSE ONLY**

Approval of initiation of enzyme-replacement therapy from \_\_\_\_\_ to \_\_\_\_\_

Approval of on-going therapy from \_\_\_\_\_ to \_\_\_\_\_

Denial Rational \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_