SoonerCare
Oklahoma Health Care Authority

Pharmacy Services
(800) 522-0114, option 4

September 2, 2019

RE: Prior Authorization of Naglazyme® (galsulfase) and Aldurazyme® (laronidase)

Effective October 1, 2019, the Oklahoma Health Care Authority (OHCA) will require a prior authorization (PA) for Naglazyme® (galsulfase) and Aldurazyme® (laronidase). A prior authorization (PA) must be submitted whether a member is starting new therapy or a member is continuing existing therapy.

The specific PA requirements for Naglyzyme® and Aldurazyme® are as follows and are located on the OHCA website at www.okhca.org/pa in the "Metabolic Disorders" therapeutic category. Please use the universal medication prior authorization form (PHARM-04) for requests through the pharmacy benefit. The universal physician/outpatient administered medication PA form (PHARM-18) should be used for requests through the medical benefit. Both of these forms can be found on the SoonerCare website at www.okhca.org/rxforms.

Aldurazyme® (Laronidase) Approval Criteria:

1. An FDA approved diagnosis of Hurler, Hurler-Scheie, or Scheie syndrome (mucopolysaccharidosis type I; MPS I) confirmed by:
   a. Enzyme assay demonstrating a deficiency of alpha-L-iduronidase (IDUA) enzyme activity; or
   b. Molecular genetic testing to confirm pathogenic mutations in the *IDUA* gene; and
2. For Scheie syndrome, the provider must document that the member has moderate-to-severe symptoms; and
3. Aldurazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
4. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Naglazyme® (Galsulfase) Approval Criteria:

1. An FDA approved diagnosis of Maroteaux-Lamy syndrome (mucopolysaccharidosis type VI; MPS VI) confirmed by:
   a. Enzyme assay demonstrating a deficiency of arylsulfatase B (ASB) enzyme activity; or
   b. Genetic testing to confirm diagnosis of MPS VI; and
2. Naglazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

All medication PA requests are submitted to the Pharmacy Prior Authorization Unit at the fax number located at the bottom of the form. Do **not** submit the request to the Medical Authorization Unit or via online through the provider portal.

If you have questions, please contact the Pharmacy Authorization Unit at (800) 522-0114, option 4.

Thank you for your continued service to Oklahoma's SoonerCare members.