Ellen M. Buettner | Chief Executive Officer
J. Kevin Stitt | Governor

OHCA 2024-06

March 19, 2024

RE: Prior Authorization of Cerezyme®, ELELYSO®, VPRIV® and ELAPRASE® – Effective April 15, 2024

Dear Provider,

As authorized by OAC 317:30-5-77.2, effective April 15, 2024, the Oklahoma Health Care Authority (OHCA) will require a prior authorization (PA) for Cerezyme® (imiglucerase), ELELYSO® (taliglucerase alfa), and VPRIV® (velaglucerase alfa) for Gaucher disease (GD). As a reminder ELAPRASE® (idursulfase) also requires a prior authorization.

If a SoonerCare member is currently being treated with any of these therapies, they will be approved for continuation of therapy. All of these therapies are available either through the pharmacy or medical benefit.

Medical claims typically lag behind the treatment date, and we may be unable to verify current therapy. To avoid a disruption in therapy, we recommend submitting a PA request for all members who receive therapy after April 1, 2024. Dates of previous doses must be listed on the PA form if a member has already received therapy.

The specific PA requirements for these medications are below and on the PA page of the OHCA website in the "Genetic Disorders" therapeutic category. A PA form is required for all claim types. The specific PA form depends on the provider supplying the medication: PHARM-04 is used for a pharmacy provider and PHARM-18 is used for a medical provider. Both forms are located on the forms page of the OHCA website.

Cerezyme (imiglucerase), ELELYSO (taliglucerase alfa) and VPRIV (velaglucerase alfa) Approval Criteria:

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- An FDA-approved diagnosis of Gaucher disease confirmed by:
  - Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤15% of normal) (results of assay must be submitted); or
  - Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted).
- Prescriber must confirm member has symptomatic (e.g., anemia, thrombocytopenia, bone disease, splenomegaly, hepatomegaly) type 1 or type 3 GD.
- Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD.
- Member's weight (kg) must be provided and must have been taken within the last four weeks to ensure accurate weight-based dosing.
- Prescriber must verify the member will not take the requested therapy concurrently with another therapy for GD.
- Initial approvals will be for the duration of six months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of one year if the member is responding well to treatment.

ELAPRASE (idursulfase) Approval Criteria:

- An FDA-approved diagnosis of Hunter syndrome (mucopolysaccharidosis type II; MPS II) confirmed by:
  - Enzyme assay demonstrating a deficiency of iduronate-2-sulfatase enzyme activity (results of assay must be submitted); or
  - Molecular genetic testing confirming a hemizygous pathogenic variant in the *IDS* gene (results of genetic testing must be submitted).
- Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS II.
- 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.
- Initial approvals will be for the duration of six months, at which time the prescriber must verify the member is responding well to the medication.

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Subsequent approvals will be for the duration of one year if the member is responding well to treatment.

All medication PA requests must be submitted to the Pharmacy Prior Authorization Unit at the fax number located at the bottom of the PA form. Do **not** submit the requests to the Medical Authorization Unit or online via the provider portal. If you have questions, please contact the Pharmacy Prior Authorization Unit at 800-522-0114, option 4.

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

Sincerely,

Traylor Rains
State Medicaid Director