| Field Name | Field Description |
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| Prior Authorization Group Description | Oxlumo (lumasiran) |
| Drugs | Oxlumo (lumasiran) |
| Covered Uses | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI). |
| Exclusion Criteria | N/A |
| Required Medical Information | See "Other Criteria" |
| Age Restrictions | N/A |
| Prescriber Restrictions | Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or consultation with one of these specialists |
| Coverage Duration | If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review. |
| Other Criteria | **Initial Authorization**<br>• Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following:<br>o Genetic testing confirming at least one mutation at the AGXT gene<br>o Liver biopsy demonstrating absent or significantly reduced AGT activity<br>• Metabolic testing demonstrating one of the following:<br>o Increased urinary oxalate excretion (≥ 0.5 mmol/1.73 $m^3$ per day[45 mg/1.73 $m^3$ per day])<br>o Increased urinary oxalate:creatinine ratio relative to normative values for age<br>o Increased plasma oxalate level (≥ 20 μmol/L)<br>• Member is concurrently using pyridoxine or has tried and failed previous pyridoxine therapy for at least 3 months, or has a medical reason for not using pyridoxine<br>• Member has no history of liver transplant<br>• Medication is prescribed at an FDA approved dose<br><br>**Reauthorization**<br>• Members previously using pyridoxine will continue to use pyridoxine, or have a medical reason for not using pyridoxine |

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| Revision/Review Date 1/2023 | • Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary or plasma oxalate levels from baseline)<br>• Medication is prescribed at an FDA approved dose<br><br>**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.** |