| Field Name | Field Description |
|-------------------------------|--|
| Prior Authorization | Treatments for Plasminogen Deficiency Type 1 (PLD1) |
| Group Description | |
| Drugs | Ryplazim (human plasma-derived plasminogen) |
| 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 |
| F 1 : G': | DI), and the Drug Package Insert (PPI). |
| Exclusion Criteria | N/A |
| Required Medical | See "Other Criteria" |
| Information A so Postrictions | NT/A |
| Age Restrictions Prescriber | N/A Prescriber must be a hometalogist, medical constinist or other |
| Restrictions | Prescriber must be a hematologist, medical geneticist, or other specialist in the treatment of rare blood or genetic disorders |
| Coverage Duration | If all of the criteria are met, the initial request will be approved for 12 |
| Coverage Duration | weeks. Reauthorization requests will be approved for 12 weeks if the |
| | member has not had a documented positive response to therapy and for |
| | 12 months if the member has had a documented positive response to |
| | therapy. If the conditions are not met, the request will be sent to a |
| | Medical Director/clinical reviewer for medical necessity review. |
| Other Criteria | **Drug is being requested through the member's medical |
| | benefit** |
| | |
| | Initial Authorization |
| | Member must have a diagnosis of PLD1 (i.e. |
| | hypoplasminogenemia) |
| | Member must have a documented history of lesions or other |
| | symptoms consistent with the diagnosis (e.g. ligneous |
| | conjunctivitis, oral, respiratory, gastrointestinal, urogenital, |
| | integumentary, or central nervous system manifestations) |
| | • Member must have baseline plasminogen activity levels ≤ 45% |
| | o If the member received plasminogen supplementation with |
| | fresh frozen plasma, prescriber attests that a 7-day washout |
| | period was performed before obtaining baseline plasminogen activity levels. |
| | 1 |
| | The request is for an FDA approved dose |
| | Reauthorization |
| | ONE of the following is true: |
| | o Member has a documented positive response to therapy |
| | (e.g. reduction in number or size of lesions, no new or |
| | recurring lesions) |
| | o Member has not had a documented positive response to |
| | therapy and ONE of the following: |
| | |

| | ■ If confirmed plasminogen activity levels are ≥ 10% |
|--------------------|---|
| | above baseline, then appropriate dosing frequency |
| | adjustments must be made. |
| | If confirmed plasminogen activity levels are < 10% |
| | above baseline, then appropriate dosing frequency |
| | adjustments must be made AND the prescriber must |
| Revision/Review | provide a medical justification as to why therapy should |
| Date 5/2022 4/2023 | be continued. |
| | • The request is for an FDA approved dose |

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.