

Field Name	<b><u>Field Description</u></b>
Prior Authorization Group Description	<b><u>Treatments for Plasminogen Deficiency Type 1 (PLD1)</u></b>
Drugs	<b><u>Ryplazim (human plasma-derived plasminogen)</u></b>
Covered Uses	<b><u>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).</u></b>
Exclusion Criteria	<b><u>N/A</u></b>
Required Medical Information	<b><u>See “Other Criteria”</u></b>
Age Restrictions	<b><u>N/A</u></b>
Prescriber Restrictions	<b><u>Prescriber must be a hematologist, medical geneticist, or other specialist in the treatment of rare blood or genetic disorders</u></b>
Coverage Duration	<b><u>If all of the criteria are met, the initial request will be approved for 12 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.</u></b>
Other Criteria	<p><b><u>**Drug is being requested through the member’s medical benefit**</u></b></p> <p><b><u>Initial Authorization</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>Member must have a diagnosis of PLD1 (i.e. hypoplasminogenemia)</u></b></li> <li>• <b><u>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)</u></b></li> <li>• <b><u>Member must have baseline plasminogen activity levels ≤ 45%</u></b> <ul style="list-style-type: none"> <li>○ <b><u>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.</u></b></li> </ul> </li> <li>• <b><u>The request is for an FDA approved dose</u></b></li> </ul> <p><b><u>Reauthorization</u></b></p> <ul style="list-style-type: none"> <li>• <b><u>ONE of the following is true:</u></b> <ul style="list-style-type: none"> <li>○ <b><u>Member has a documented positive response to therapy (e.g. reduction in number or size of lesions, no new or recurring lesions)</u></b></li> </ul> </li> </ul>

<p>Revision/Review Date 5/2022</p>	<ul style="list-style-type: none"> <li>○ <u>Member has not had a documented positive response to therapy and ONE of the following:</u> <ul style="list-style-type: none"> <li>▪ <u>If confirmed plasminogen activity levels are <math>\geq 10\%</math> above baseline, then appropriate dosing frequency adjustments must be made.</u></li> <li>▪ <u>If confirmed plasminogen activity levels are <math>&lt; 10\%</math> above baseline, then appropriate dosing frequency adjustments must be made AND the prescriber must provide a medical justification as to why therapy should be continued.</u></li> </ul> </li> <li>• <u>The request is for an FDA approved dose</u></li> </ul> <p><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</u></p>
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