

<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Lamzede</u>
<u>Drugs</u>	<u>Lamzede (velmanase alfa-tycv)</u>
<u>Covered Uses</u>	<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), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</u>
<u>Exclusion Criteria</u>	<u>N/A</u>
<u>Required Medical Information</u>	<u>“See Other Criteria”</u>
<u>Age Restrictions</u>	<u>N/A</u>
<u>Prescriber Restrictions</u>	<u>Prescribed by or in consultation with a specialist in the treatment of alpha-mannosidosis or other lysosomal storage disorders</u>
<u>Coverage Duration</u>	<u>If all of the criteria are met, the request will be approved for 12 months</u>
<u>Other Criteria</u>	<p><u>**Drug is being requested through the member’s medical benefit**</u></p> <p><u>Initial Authorization</u></p> <ul style="list-style-type: none"> <li>• <u>Diagnosis of alpha-mannosidosis as confirmed by one of the following:</u> <ul style="list-style-type: none"> <li>○ <u>Deficiency in alpha-mannosidase enzyme levels or activity in blood leukocytes</u></li> <li>○ <u>DNA testing</u></li> </ul> </li> <li>• <u>Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis</u></li> <li>• <u>Patient’s weight</u></li> <li>• <u>Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</u></li> </ul> <p><u>Reauthorization</u></p> <ul style="list-style-type: none"> <li>• <u>Patient has demonstrated a clinical response (i.e., reduction in serum oligosaccharide concentrations, stabilization or improvement in 3-minute stair climbing test [3MSCT], 6-minute walking test [6-MWT], forced vital capacity [FVC], etc.)</u></li> <li>• <u>Prescriber attests that medication will only be used to treat non- central nervous system manifestations of alpha-mannosidosis</u></li> <li>• <u>Patient’s weight</u></li> <li>• <u>Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</u></li> </ul>
<u>Revision/Review Date 4/2024</u>	

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