

PHARMACY PRE-AUTHORIZATION CRITERIA

DRUG (S)	Zavesca (miglustat)
POLICY #	22113
INDICATIONS	<p>Zavesca is indicated for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option. (e.g. due to constraints such as allergy, hypersensitivity, or poor venous access).</p>
CRITERIA	<p>ConnectiCare considers Zavesca to be medically necessary for patients who meet the following criteria:</p> <ul style="list-style-type: none"> • Patient has clinically documented type 1 Gaucher disease <p>AND</p> <p>Prescribed by, or after consultation with, a physician that specializes in the treatment of inherited metabolic disorders</p> <p>AND</p> <ul style="list-style-type: none"> • Patient must be ≥ 18 years of age <p>AND</p> <ul style="list-style-type: none"> • Patient is not a candidate for enzyme replacement.
LIMITATIONS	<p>If the above criteria are met initial authorization will be limited to 3 months. Subsequent approval (up to 1 year) will require physician documentation of efficacy and stability.</p>
REFERENCES	<p>1. Zavesca full prescribing information. Actelion Pharmaceuticals US inc. South San Francisco, CA</p>
P&T REVIEW HISTORY	<p>3/04, 3/05, 12/06, 6/07, 6/08, 9/09, 4/10, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 5/16, 5/17, 5/18, 5/19</p>
REVISION RECORD	<p>11/12, 3/15, 5/18, 5/19 11/19- removed Cerezyme, Elelyso, & Vpriv - adopted EH Medical Policy 12/19- removed Cerdelga – adopted/aligned with EH policy, changed policy name from Gaucher to Zavesca</p>