MIGLUSTAT

Generic	Brand	HICL	GCN	Exception/Other
MIGLUSTAT	ZAVESCA	25098		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient being treated for type 1 (non-neuronopathic) Gaucher disease?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient 18 years of age or older?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is enzyme replacement therapy not a therapeutic option for this patient due to constraints such as allergy, hypersensitivity, or poor venous access?

   If yes, **approve for up to 12 months with a quantity limit of #90 capsules per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   DENIAL TEXT: Approval requires a diagnosis of type 1 Gaucher disease in patients 18 years of age or older for whom enzyme replacement therapy is not an option.

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RATIONALE
Ensure that Zavesca is being used to treat patients with type 1 Gaucher disease.

FDA APPROVED INDICATION
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).

REFERENCES

- Actelion Pharmaceuticals. Zavesca package insert. South San Francisco. November 2010.
- Elstein D, Dweck A, Attias D et al. Oral maintenance clinical trial with miglustat for type I Gaucher disease: switch from or combination with intravenous enzyme replacement. Blood. 2007;110:2296-2301.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/12
Created: 05/05
Client Approval: 08/12
P&T Approval: 08/12