



MARKET EVENTS CLINICAL POLICY

POLICY: Zavesca Market Events Clinical Policy

TAC APPROVAL DATE: 05/15/2019

DRUGS AFFECTED: Zavesca® (miglustat capsules – Actelion Pharmaceuticals)

OVERVIEW

Gaucher disease is a rare autosomal recessive, inherited, lysosomal storage disorder caused by a deficiency of the lysosomal enzyme β -glucocerebrosidase. Zavesca (generic miglustat [AB-rated generic to Zavesca]) is an SRT agent indicated for long-term therapy in patients with a confirmed diagnosis of Type 1 Gaucher disease. Zavesca is indicated as monotherapy for the treatment of adult patients with mild to moderate Gaucher disease type 1 for whom enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access).¹

POLICY STATEMENT

This policy requires that the patient meet ESI Standard Prior Authorization (PA) criteria and additionally requires the patient to try generic miglustat, when clinically appropriate, prior to the approval of the brand Zavesca. All approvals are provided for 1 year in duration.

Automation: None.

RECOMMENDED EXCEPTION CRITERIA

Trade Name	Exception
Zavesca	<p>1. Approve if the patient meets the following criteria (A and B):</p> <p>A. Patient meets the ESI Standard <i>Gaucher Disease Substrate Reduction Therapy – Zavesca Prior Authorization (PA)</i> criteria; AND</p> <p>B. Patient has tried generic miglustat OR brand Zavesca is being requested due to a formulation difference in the inactive ingredient(s) [e.g., preservatives] between the brand and the bioequivalent generic product, which, per the prescribing physician has or would result in a significant allergy or serious adverse reaction.</p>

REFERENCES

1. Zavesca® [prescribing information]. South San Francisco, CA: Actelion Pharmaceuticals US Inc.; November 2017.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New policy	--	5/23/2018
Annual revision	No criteria changes.	5/15/2019

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TAC – Therapeutic Assessment Committee; * For further summary of criteria changes, refer to respective Therapeutic Assessment Committee (TAC) minutes available at:
<http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>.

05/15/2019

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