

## MARKET EVENTS CLINICAL POLICY

**POLICY:** Zavesca Market Events Clinical Policy

- Zavesca® (miglustat capsules – Actelion Pharmaceuticals)

**REVIEW DATE:** 05/04/2022

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### OVERVIEW

Gaucher disease is caused by a deficiency in the lysosomal enzyme  $\beta$ -glucocerebrosidase.<sup>1</sup> This enzyme is responsible for the breakdown of glucosylceramide into glucose and ceramide. In Gaucher disease, deficiency of the enzyme  $\beta$ -glucocerebrosidase results in the accumulation of glucosylceramide substrate in lysosomal compartment of macrophages, giving rise to foam cells or “Gaucher cells.” Zavesca is a specific inhibitor of the enzyme glycosylceramide synthase, which is responsible for producing the substrate glucosylceramide.<sup>1</sup> By functioning as a substrate reduction therapy, Zavesca allows the residual activity of the deficient glucocerebrosidase enzyme to be more effective.

### POLICY STATEMENT

This Market Events policy requires that the patient meet the respective standard *Prior Authorization Policy* criteria. The policy also directs 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 Criteria
Zavesca	<ol style="list-style-type: none"><li>1. Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B):<ol style="list-style-type: none"><li>A) Patient meets the standard <i>Gaucher Disease – Substrate Reduction Therapy – Miglustat Prior Authorization</i> criteria; AND</li><li>B) Patient has tried generic miglustat AND brand Zavesca is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic, which, per the prescriber has or would result in a significant allergy or serious adverse reaction.</li></ol></li></ol>

### REFERENCES

1. Zavesca® capsules [prescribing information]. South San Francisco, CA: Actelion; January 2021.

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