# Preferred Specialty Management
# Zavesca® (miglustat capsules)

## Table of Contents

National Formulary Medical Necessity .....1
Conditions Not Covered.....2
Background.....2
References .....2
Revision History.....2

## Product Identifier(s)

59775, 62192

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## National Formulary Medical Necessity

Drugs Affected:
- Miglustat capsules
- Zavesca® (miglustat capsules)

This policy requires that the individual meet the respective standard *Prior Authorization Policy* criteria. The policy also directs the individual to try generic miglustat, when clinically appropriate, prior to the approval of the brand Zavesca. All approvals are provided for 1 year in duration.

**Preferred Product(s):** miglustat
**Non-Preferred Product(s):** Zavesca

**Cigna covers Non-Preferred Products as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:**

| Non-Preferred Product | Exception |
|---|---|
| Zavesca | **1.** Approve for 1 year if the individual meets BOTH of the following (A and B): |

| Non-Preferred Product | Exception |
|---|---|
| | **A)** Individual meets the standard *Gaucher Disease Substrate Reduction Therapy – Miglustat (Zavesca) Prior Authorization (PA)* criteria; AND<br>**B)** Individual 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. |

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

**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 a glucosylceramide synthase inhibitor. Zavesca (miglustat) 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]

## References


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


## Revision History

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | No criteria changes. | 5/13/2020 |
| Annual Revision | **Zavesca:** For the exception criteria, difference in dyes and fillers were added as examples for reason the brand product may be requested. The assessment was changed from according to the prescribing physician to more generally be according to the prescriber. | 05/12/2021 |
| Selected Revision | **Zavesca:** For the exception criteria, it was updated that the patient is required to try generic miglustat AND brand Zavesca is being requested due to a formulation difference in the inactive ingredient(s) between the Brand and the bioequivalent generic; previously the criterion was OR. | 05/19/2021 |


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