

## FORMULARY EXCEPTION POLICY

**POLICY:** Zavesca® (miglustat capsules – Actelion Pharmaceuticals)

**DATE CREATED:** 08/05/2020

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**Documentation:** Documentation will be required for patients requesting brand Zavesca where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or laboratory data.

### CRITERIA

1. **Gaucher Disease Type I.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
  - A) If Zavesca is prescribed by or in consultation with a geneticist, endocrinologist, metabolic disorder sub-specialist, or a physician who specializes in the treatment of Gaucher Disease or related disorders; AND
  - B) Patient has tried BOTH of the products, Cerdelga (eliglustat capsules) **[documentation required]** and generic miglustat **[documentation required]**; AND
  - C) Brand Zavesca is being requested due to a formulation difference in the inactive ingredient(s) [e.g., preservatives] between the Brand and the bioequivalent miglustat generic product, which, per the prescribing physician has or would result in a significant allergy or serious adverse reaction.

### ISTORY

| Type of Revision | Summary of Changes* | Effective Date |
|------------------|---------------------|----------------|
| New Policy       | --                  | 07/01/2019     |
| Annual revision  | No criteria changes | 08/05/2020     |