EXPRESS SCRIPTS®

FORMULARY EXCEPTION POLICY

POLICY: Zavesca® (miglustat capsules – Actelion Pharmaceuticals)

DATE CREATED: 07/01/2019

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)** Zavesca if the 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