

HealthAlliance**MEDICARE**

PURPOSE OF THE POLICY

To establish guidelines for coverage of Zavesca®

STATEMENT OF THE POLICY

Zavesca (miglustat) will be covered for the treatment of the FDA approved indication, Type 1 Gaucher's Disease when the following criteria are met and after proper B v D decisions have been made.

Policy applies to new starts only for Medicare Part D members

PROCEDURES

1. Inclusion criteria

- 1.1 Contraindicated to enzyme replacement therapy or member unable to receive intravenous infusion.
- 1.2 Negative pregnancy test

2. Exclusion criteria

- 2.1 Patient is currently on enzyme replacement therapy.
- 2.2 Pregnancy
- 2.3 Severe renal impairment (CrCl <30 mL/min/1.73 m²)
- 2.4 Patient < 18 yo or >65 yo.

3. References

- 3.1 Micromedex Drug Evaluation
- 3.2 Zavesca [product labeling]. Actelion, Ltd; July 2003
- 3.3 Drug Monograph Services, Wolters Kluwer Health, Inc., October 2003