JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS068
		Effective Date	04/01/2009
		Review Date	07/18/2018
	Subject **Xenazine (Tetrabenazine) and Austedo**	*Revision Date*	12/02/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: austedo, tetrabenazine

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I. POLICY

A. Tetrabenazine (Xenazine) and Austedo (deutetrabenazine) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Tetrabenazine may be approved for the following:
   1. A diagnosis of chorea associated with Huntington's disease

B. Austedo may be approved for the following:
   1. A diagnosis of chorea associated with Huntington's disease AND documented trial and failure of generic tetrabenazine
   2. A diagnosis of tardive dyskinesia

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 12 months
   1. Tetrabenazine may be approved up to a maximum dose of 100 mg/day.
   2. Austedo may be approved up to a maximum dose of 48mg/day

B. Continuation of therapy may be approved in 12-month intervals with clinical documentation supporting continued benefit.

IV. EXCLUSIONS

A. Tetrabenazine and Austedo will NOT be approved for:
   1. Concomitant use with each other, or Ingrezza (valbenazine)
   2. Patients who are suicidal or have suicidal ideations
   3. Patients with untreated or inadequately treated depression
   4. Patients with hepatic impairment
   5. Patients who are currently using a monoamine oxidase inhibitor

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6. Patients who are currently using reserpine or have used reserpine in the past 20 days
7. Any indications or uses that are not FDA-approved or guideline-supported

B. The safety and efficacy of tetrabenazine and Austedo have not been established in pediatric patients.

C. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Xenazine: Prescribing Information. Washington, DC: Prestwick Pharmaceuticals, Inc.; September 2017
2. Austedo: Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; June 2021

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
03/30/2016	Removed background information & layout update
07/19/2017	Addition of clinical criteria for Austedo
07/27/2017	Updated Exclusions section regarding physician samples
07/18/2018	Addition of clinical criteria for Austedo's tardive dyskinesia indication
12/02/2021	Updated policy layout

Review/Revision Dates: 04/13/2009, 03/30/2016, 07/19/2017, 07/27/2017, 07/18/2018, 12/02/2021

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