

## DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Vesicular Monoamine Transporter Type 2 Inhibitors Drug Quantity Management Policy – Per Rx
- Austedo® (deutetrabenazine tablets – Teva)
  - Ingrezza® (valbenazine capsules – Neurocrine Biosciences)
  - Xenazine® (tetrabenazine tablets – Lundbeck, generic)

**REVIEW DATE:** 10/12/2022

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### OVERVIEW

Austedo, Ingrezza, and tetrabenazine tablets are vesicular monoamine transporter type 2 inhibitors.<sup>1-3</sup>

Austedo is indicated in adults with:<sup>1</sup>

- **Chorea associated with Huntington’s disease.**
- **Tardive dyskinesia.**

Ingrezza is indicated for the treatment of **tardive dyskinesia** in adults.<sup>2</sup>

Tetrabenazine, is indicated for the treatment of **chorea associated with Huntington’s disease** in adults.<sup>3</sup>

### Dosing

#### Austedo

The recommended starting dose of Austedo is 12 mg/day (6 mg twice daily [BID]).<sup>1</sup> The dose may be increased at weekly intervals in increments of 6 mg/day, based on reduction of chorea or tardive dyskinesia and tolerability, up to a maximum 48 mg/day. Total daily dosages of  $\geq 12$  mg should be administered in two divided doses. In patients switching from tetrabenazine to Austedo, the starting dose is based on the patient’s prior tetrabenazine dose ranging from 6 mg once daily (QD) to 24 mg BID. Doses are adjusted on a weekly basis.<sup>1</sup>

In patients who are poor cytochrome P450 (CYP)2D6 metabolizers or receiving strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine), the total daily dosage of Austedo should not exceed 36 mg (maximum 18 mg BID).<sup>1</sup>

#### Ingrezza

The recommended starting dose of Ingrezza is 40 mg QD and may be increased to 80 mg/day after 1 week.<sup>3</sup> A dose of 40 mg or 60 mg QD may be considered depending on response and tolerability. The recommended dose for patients with moderate or severe hepatic impairment (Child-Pugh score 7 to 15) is 40 mg QD. The dose of Ingrezza should be reduced to 40 mg QD in the following patient populations: CYP2D6 poor metabolizers, patients receiving CYP3A4 inhibitors, or patients receiving strong CYP2D6 inhibitors.

#### Tetrabenazine tablets (Xenazine, generic)

The starting dose is 12.5 mg QD in the morning.<sup>2</sup> After 1 week, the dose can be increased to 25 mg/day (given as 12.5 mg BID) and up-titrated at weekly intervals by 12.5 mg daily, to allow the identification of a tolerated dose that reduces chorea. If a dose of 37.5 mg/day to 50 mg/day is needed, it should be given in a three times a day (TID) regimen. The maximum recommended single dose is 25 mg.

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Patients who require a dose > 50 mg/day should first be tested and genotyped to determine if they are poor metabolizers or extensive metabolizers by their ability to express the drug metabolizing enzyme, CYP2D6.<sup>2</sup> Patients who are identified as extensive or intermediate metabolizers of CYP2D6, who need doses > 50 mg/day, should be up-titrated at weekly intervals by 12.5 mg/day, to allow the identification of a tolerated dose that reduces chorea. Doses > 50 mg/day should be given in a TID regimen. The maximum recommended daily dose is 100 mg and the maximum recommended single dose is 37.5 mg. In poor metabolizers, the initial dose and titration is similar to extensive metabolizers except that the recommended maximum single dose is 25 mg, and the recommended daily dose should not exceed a maximum of 50 mg/day. The total dose of tetrabenazine should not exceed 50 mg/day (and single dose should not exceed 25 mg) when used with strong CYP2D6 inhibitors such as quinidine or antidepressants (e.g., fluoxetine, paroxetine).

### Availability

Austedo is available as 6 mg, 9 mg, and 12 mg tablets in bottles containing 60 tablets.<sup>1</sup> Tablets should not be chewed, crushed or split.

Ingrezza is available as 40 mg, 60 mg and 80 mg capsules in bottles containing 30 capsules.<sup>2</sup> Ingrezza is also available as a an initiation blister pack containing 28 capsules (7 x 40 mg capsules and 21 x 80 mg capsules).

Tetrabenazine is available as 12.5 mg and 25 mg tablets in bottles containing 112 tablets.<sup>3</sup>

### POLICY STATEMENT

This Drug Quantity Management program has been developed to promote dose consolidation, prevent stockpiling and waste, and address the potential order entry error of the vesicular monoamine transporter type 2 inhibitors. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

**Automation:** None.

### Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Austedo® (deutetrabenazine tablets)*	6 mg tablets	60 tablets	180 tablets
	9 mg tablets	120 tablets	360 tablets
	12 mg tablets	120 tablets	360 tablets
Ingrezza® (valbenazine capsules)‡	40 mg capsules	30 capsules	90 capsules
	60 mg capsules	30 capsules	90 capsules
	80 mg capsules	30 capsules	90 capsules
	Initiation Blister Pack (7 x 40 mg capsules + 21 x 80 mg capsules)	28 capsules	28 capsules
Xenazine® (tetrabenazine tablets, generic)†	12.5 mg tablets	120 tablets	360 tablets
	25 mg tablets	60 tablets	180 tablets

\* This is a quantity sufficient for a 30-day supply at the recommended dosing; ‡ This quantity will supply enough medication for a 30-day supply for the 40 mg, 60 mg or 80 mg capsules. For the titration pack, it will supply a quantity sufficient to initiate therapy according to the recommended titration schedule for 28 days; † This is a quantity sufficient to supply enough medication for a 30-day supply for daily doses of ≤ 50 mg. Exceptions are made for patients receiving doses between > 50 mg and ≤ 100 mg.

### CRITERIA

Austedo

No overrides recommended.

Tetrabenzine (Xenazine, generic) 12.5 mg tablets

1. If the patient is an extensive or intermediate metabolizer of cytochrome P450 (CYP)2D6 AND needs a dose greater than 50 mg/day, approve the quantity requested not to exceed 240 tablets per dispensing at retail and not to exceed 720 tablets per dispensing at home delivery.

Tetrabenzine (Xenazine, generic) 25 mg tablets

1. If the patient is an extensive or intermediate metabolizer of cytochrome P450 (CYP)2D6 AND needs a dose greater than 50 mg/day, approve the quantity requested not to exceed 120 tablets per dispensing at retail and not to exceed 360 tablets per dispensing at home delivery.

Ingrezza 40 mg capsules

1. If the patient is initiating therapy and is increasing the daily dose from 40 mg to 80 mg daily. Approve a one-time override for the requested quantity not to exceed 60 capsules at retail and home delivery.

Ingrezza 60 mg, 80 mg capsules

No overrides recommended.

Ingrezza Initiation Pack (7 x 40 mg – 7 capsules, 21 x 80 mg – 21 capsules)

No overrides recommended.

**REFERENCES**

1. Austedo® tablets [prescribing information]. North Wales, PA: Teva; May 2022.
2. Ingrezza® capsules [prescribing information]. San Diego, CA: Neurocrine Biosciences; April 2021.
3. Xenazine® tablets [prescribing information]. Deerfield, IL: Lundbeck; November 2019.