AUSTEDO® XR
(deutetrabenazine)
extended-release tablets
AUSTEDO®
(deutetrabenazine) tablets

Letter of Medical Necessity Template Instructions

A Letter of Medical Necessity may be helpful to patients in the following situations:

- When an initial request for coverage is denied
- When a patient needs a product that would normally be subject to step therapy or prior authorization
- When a product is prescribed that is not routinely available within a payer's formulary or is only available at a higher copay tier
- If a payer requires healthcare providers to support a prescription with additional information to ensure patient access to therapy

Payers vary in their requirements for determining medical necessity. The following page is a template letter that healthcare providers can cut and paste onto their office letterhead. The letter includes the type of information that payers may require to establish medical necessity, such as:

- The patient's diagnosis, condition, and medical history, including AIMS score if applicable
- Information about your patient's previous therapies and his/her response to those therapies
- A summary of your opinion about the patient's prognosis without treatment
- Other documentation that supports your position

Please note that this template is intended only as an example. Teva recommends confirming the information that is required to include in a medical necessity letter with individual payers.

Physician Letterhead

[Insurance Company]
[Address Line 1]
[Address Line 2]

Patient: [Patient's first and last name]
Patient DOB: [Patient's date of birth]
Policy ID: [Insurance ID #]
Policy Group: [Insurance Group #]

[Date]

Re: [AUSTEDO® XR (deutetrabenazine) extended-release tablets/AUSTEDO® (deutetrabenazine) tablets] coverage

Dear: [Payer Contact Name, Medical/Pharmacy Director], [Department]

I am writing on behalf of my patient, [patient's name], born [date of birth], who has a diagnosis of [Chorea associated with Huntington's Disease, G10 Huntington's Disease] or [Tardive Dyskinesia G24.01] to formally document the medical necessity for treatment with [AUSTEDO XR/AUSTEDO]. This letter provides information about the patient's medical history, diagnosis, and treatment plan with [AUSTEDO XR/AUSTEDO].

Patient's Medical History and Treatment Rationale:

- Patient's medical history, diagnosis, and current condition (e.g. signs, symptoms, functioning): [Provide a brief statement about the patient's diagnosis and medical history, including any underlying health issues that affect your treatment selection, date of diagnosis, and quality of life]
- Prior treatments and response to those treatments: [If applicable, provide a list of current and past medications, as well as reasons for not prescribing a medication (e.g. contraindications, drug interactions, lack of efficacy) and a summary of the patient's experience with each medication, including clinical outcome, adverse drug reactions, and length of therapy]
- Include a summary why, based on your clinical judgment, your patient requires treatment with [AUSTEDO XR/ AUSTEDO]
- Include a summary of why, based on your clinical judgement, the patient requires the QD formulation [if applicable, provide commentary on once daily administration, medication adherence/compliance, and/or requirements for taking with or without food].

Summary of Rationale for Treatment:
In summary, considering the patient's history, condition and the full Prescribing Information, use of [AUSTEDO XR/ AUSTEDO] at this time is appropriate and medically necessary. Please contact my office at [office phone number] if any additional information is required.

Sincerely,

[Physician's name]
[Physician's NPI, TIN, and insurance identifying group number]

Include enclosures as appropriate, such as excerpts from the patient's medical record, relevant treatment guidelines, Prescribing Information for AUSTEDO XR/AUSTEDO, and relevant clinical data