November 5, 2020

Dear West Virginia Medicaid Drug Utilization Review Committee:

Thank you for the opportunity to discuss the current WV prior authorization criteria for INGREZZA® (valbenazine) capsules which is indicated for the treatment of adults with tardive dyskinesia TD.

INGREZZA® (valbenazine) is the first FDA-approved treatment indicated for adults with tardive dyskinesia (TD) and has long term safety and efficacy data. We respectfully ask the committee to consider adding Ingrezza as a first line treatment for TD.

Tardive dyskinesia (TD) is an often persistent and disruptive condition associated with prolonged exposure to dopamine receptor blocking agents, including antipsychotic and antiemetic drugs.[2,3]

Recommendations from a 2018 systematic review article state that VMAT2 inhibitors must be recommended as the first-line treatment for TD (Level A recommendation- the highest level of evidence)[4] The treatment of TD with clonazepam was given a Level B recommendation which is defined as "Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population and requires at least one Class I study or two consistent Class II studies.[4] The treatment of TD with amantadine or tetrabenazine was given a Level C recommendation, which is defined as "Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population and requires at least one Class II study or two consistent Class III studies.[4]

In addition, the 2020 American Psychiatric Association (APA) Schizophrenia Guideline published this past September, recommended VMAT2 inhibitors as 1st line therapy for the treatment of TD. The 2020 APA Schizophrenia Guideline also noted that there is insufficient evidence to support a guideline statement on the use of amantadine or clonazepam for individuals with TD.[5]

The efficacy and safety of INGREZZA® were established in multiple clinical trials with adults with TD and stable schizophrenia, schizoaffective disorder or a mood disorder. The Phase III pivotal randomized clinical trial, KINECT 3, included 234 adults with TD. Patients were allowed to remain on their usual stable doses of psychotropic medications throughout the trial. The primary efficacy endpoint, mean change in Abnormal Involuntary Movement Scale (or AIMS) score for INGREZZA® 80 mg from baseline to Week 6 relative to placebo, was met.[6]

- After 6 weeks, 198 patients continued in a blinded open-label long-term extension study for 42 weeks, followed by a 4-week washout period. At Week 48 in the long-term extension phase, reductions in TD severity based on AIMS were maintained in both INGREZZA dose groups; -4.9 points in 80 mg/day group and -3.0 points in 40 mg/day.[7]

INGREZZA has no boxed warnings. INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. INGREZZA has three warnings and precautions, including somnolence, potential for prolongation of QT interval -although the degree is not clinically significant at concentrations expected with recommended dosing- and parkinsonism in patients with TD. All 3 of these have been observed with other VMAT2 inhibitors. INGREZZA safety was evaluated

in 3 six-week double blind placebo-controlled studies and included 445 patients. The most commonly reported adverse reaction greater than or equal to 5%, and twice the rate of placebo was somnolence.[1]

In a post hoc analysis of pooled data from INGREZZA® clinical trials, safety and efficacy were similar in older patients compared to younger patients and there is no required dose adjustment for geriatric patients.[8] No dose adjustment is required for patients with mild, moderate or severe renal impairment.[1]

The FDA-recommended dosing for INGREZZA is 40mg once daily for one week, increasing to the recommended dose of 80mg thereafter. Continuation of 40 mg once daily may be considered for some patients. INGREZZA is taken orally, with or without food, and at any time of day.[1]

In summary, INGREZZA is an effective once daily treatment for adults with TD with long-term safety and efficacy data up to 48 weeks.[1] We respectfully request that the committee add INGREZZA as a preferred agent for the treatment of TD in adults.

I welcome the opportunity for additional discussion regarding ensuring appropriate access to INGREZZA® (valbenazine) for the treatment of adults with TD.

Kind regards,
Mark

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