

Abnormal Involuntary Movement Scale (AIMS) Assessment Tool

Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding the abnormal involuntary movement scale (AIMS) assessment tool.

The AIMS is a 12-item clinician-rated, non-linear scale often used as a surveillance tool to assess the severity of tardive dyskinesia (TD) in patients exposed to antipsychotic medications, either in clinical studies or medical practice. It is not a diagnostic tool. Items 1–7 assess severity of dyskinesia by body region (buccal/oral, extremities, trunk). They are rated on a 5-point scale (0=none; 1=minimal; 2=mild; 3=moderate; 4=severe). Total dyskinesia score is usually defined as the sum of severity scoring for items 1–7, with a decreased AIMS total score from baseline indicating improvement in TD. Items 8–10 assess examiner-rated global severity and patient's awareness of movements and associated distress. Items 11–12 are questions concerning problems with teeth and/or dentures.^{1,2,3}

The additional descriptors in the attached AIMS Document regarding amplitude and frequency of symptoms are unique to the INGREZZA® (valbenazine) clinical trials in adults with TD.4

This letter and the enclosed material are provided in response to your unsolicited medical information inquiry. Please feel free to contact Neurocrine Medical Information at (877) 641-3461 or medinfo@neurocrine.com if you would like to request additional information.

References:

- Guy W. ECDEU Assessment Manual for Psychopharmacology: Revised (DHEW publication number ADM 76-338).
- 2. Lane RD, et al. Assessment of tardive dyskinesia using the Abnormal Involuntary Movement Scale. *J Nerv Ment Dis.* 1985;173(6):353-357.
- 3. Colosimo C, et al. Task force report on scales to assess dyskinesia in Parkinson's disease: critique and recommendations. *Mov Disord*. 2010;25(9):1131-1142.
- 4. INGREZZA [package insert]. Neurocrine Biosciences, Inc., San Diego, CA.

MED-MI-TD-US-0071_v6



Abnormal Involuntary Movement Scale (AIMS)

The descriptors in the table below are unique to the valbenazine clinical trials in adults with TD and include a more detailed explanation of how each severity level (0 to 4) is scored. The additional details include the amplitude and frequency of symptoms, which may help providers more accurately assess and assign an appropriate score for each body region.

| Score | Descriptors (For items 1–7) ^{2,3} |
|-------|--|
| 0 | No dyskinesia |
| 1 | Minimal or slight dyskinesia: Low amplitude, present during some but not most of the exam |
| 2 | Mild dyskinesia: Low amplitude and present during most of the exam (or moderate amplitude and present during some of the exam) |
| 3 | Moderate dyskinesia: Moderate amplitude and present during most of exam |
| 4 | Severe dyskinesia: Maximal amplitude and present during most of exam |

| Facial and Oral Movements ² | | None | Minimal | Mild | Moderate | Severe | | | |
|--|--|-----------------|---------|------|----------|--------|--|--|--|
| 1. | Muscles of Facial Expression e.g., movements of forehead, eyebrows, pe cheeks, include frowning, blinking, smiling, | 0 | 1 | 2 | 3 | 4 | | | |
| 2. | Lips and Perioral Area e.g., puckering, pouting, smacking | 0 | 1 | 2 | 3 | 4 | | | |
| 3. | Jaw e.g., biting, clenching, chewing, mouth opening, lateral movement | 0 | 1 | 2 | 3 | 4 | | | |
| 4. | Tongue Rate only increase in movement both in and out of mouth, NOT inability to sustain movement. | 0 | 1 | 2 | 3 | 4 | | | |
| Ext | remity Movements ² | | | | | | | | |
| 5. | Upper (arms, wrists, hands, fingers) Include choreic movements (i.e., rapid, obje purposeless, irregular, spontaneous), athetc (i.e., slow, irregular, complex, serpentine). DO NOT include tremor (i.e., repetitive, regu | 0 | 1 | 2 | 3 | 4 | | | |
| 6. | Lower (legs, knees, ankles, toes) e.g., lateral knee movement, foot tapping, he foot squirming, inversion and eversion of foc | 0 | 1 | 2 | 3 | 4 | | | |
| Trunk Movements ² | | | | | | | | | |
| 7. | Neck, shoulders, hips e.g., rocking, twisting, squirming, pelvic gyrations | 0 | 1 | 2 | 3 | 4 | | | |
| Glo | bal Judgments ² | None, Normal | Minimal | Mild | Moderate | Severe | | | |

MED-MI-TD-US-0071_v6 2



| 8. | Severity of abnormal movements overall | 0 | 1 | 2 | 3 | 4 | | |
|----------------------------|---|---|---|---|----|-----|--|--|
| 9. | Incapacitation due to abnormal movements | 0 | 1 | 2 | 3 | 4 | | |
| 10. | Patient's awareness of abnormal movements (rate only patient's report) 0=No awareness, 1=Aware, no distress, 2=/ distress, 3=Aware, moderate distress, 4=Aw severe distress | 0 | 1 | 2 | 3 | 4 | | |
| Dental Status ² | | | | | | | | |
| 11. | Current problems with teeth and/or dentures | | | | No | Yes | | |
| 12. | Does the patient usually wear dentures? | | | | No | Yes | | |

MED-MI-TD-US-0071_v6 3