

Appendix e-1. Assessment tools for patient-reported outcomes in the core and endophenotype modules in CaMEO

PHQ-9 (9-item Patient Health Questionnaire)

The PHQ-9 is based on 9 items assessing *Diagnostic and Statistical Manual of Mental Disorders, 4th edition* (DSM-IV)¹ criteria for Major Depressive Disorder with total scores ranging from 0 to 27, as each of the 9 items can be scored from 0 (not at all) to 3 (nearly every day). Depression severity is characterized by score total, with 0 to 4 for minimal, 5 to 9 for mild, 10 to 14 for moderate, 15 to 19 for moderately severe, and 20 to 27 for severe.²

GAD-7 (Generalized Anxiety Disorder 7-item scale)

The GAD-7 consists of 7 items assessing DSM-IV criteria for Generalized Anxiety Disorder with total scores ranging from 0 to 21, as each of the 7 items is scored from 0 to 3. Anxiety severity is considered minimal for scores of 0 to 4, mild for 5 to 9, moderate for 10 to 14, and severe for 15 to 21.³

MIDAS (Migraine Disability Assessment)

The MIDAS score is based on 5 disability questions in 3 areas, assessed over the preceding 3 months, with scores of 0 to 5 representing Grade I minimal or infrequent disability; 6 to 10, Grade II mild or infrequent disability; 11 to 20, Grade III moderate disability; and 21 or greater, Grade IV severe disability.⁴

MIBS-4 (Migraine Interictal Burden Scale)

The MIBS-4 is a 4-item scale asking about interictal burden where the summed score of 0 is categorized as none, 1 to 2 as mild, 3 to 4 as moderate, and 5 or more as severe interictal burden.⁵ In this analysis, the PHQ-9, GAD-7, MIDAS, and MIBS-4 patient-reported outcomes were dichotomized to “none/minimal/mild” or “moderate to severe” based on total scores.

ASC-12 (12-item Allodynia Symptom Checklist)

The ASC-12 includes 12 items that assess the frequency of cutaneous allodynia symptoms associated with migraine attacks with a sum score that ranges from 0 to 24.⁶ Allodynia was characterized in this analysis as present with an ASC-12 score of 3 or greater.

MSSS (Migraine Symptom Severity Score)

The MSSS is a composite index based on the frequency of 7 primary migraine features (unilateral pain, pulsatile pain, moderate or severe pain intensity, routine activities worsening pain, nausea, photophobia, and phonophobia) with responses ranging from 1 to 4 and the overall sum score ranging from 7 to 28. Migraine symptom severity was assessed in this analysis with MSSS score as a continuous variable.⁷

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 4th ed. Washington, DC: American Psychiatric Press; 2000.
2. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606-613.
3. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092-1097.
4. Stewart WF, Lipton RB, Dowson AJ, Sawyer J. Development and testing of the Migraine Disability Assessment (MIDAS) Questionnaire to assess headache-related disability. *Neurology* 2001;56:S20-S28.
5. Buse DC, Rupnow MF, Lipton RB. Assessing and managing all aspects of migraine: migraine attacks, migraine-related functional impairment, common comorbidities, and quality of life. *Mayo Clin Proc* 2009;84:422-435.
6. Lipton RB, Bigal ME, Ashina S, et al. Cutaneous allodynia in the migraine population. *Ann Neurol* 2008;63:148-158.
7. Manack Adams A, Serrano D, Buse DC, et al. The impact of chronic migraine: The Chronic Migraine Epidemiology and Outcomes (CaMEO) Study methods and baseline results. *Cephalalgia* 2015;35:563-578.