MDD Advisory Group Meeting
Meeting Summary

January 11, 2021

Attendees:
Gretchen Wartman, National Minority Quality Forum
Jessica Kennedy, Mental Health America
Susan dosReis, PAVE
Karen Moseley, HERO
Paul Fronstin, Employee Benefit Research Institute
Benjamin Miller, Well Being Trust
Mohannad Kusti, Optimal Workplace and Environmental Wellness Corporation
Julia Slejko, PAVE
Raquel Halfond, APA
Jordana Schmier, Pharmerit
Becky Yowell, APA
Iman Nourhussein, Pharmerit
Phyllis Foxworth, Depression and Bipolar Support Alliance
Brian Gifford, Integrated Benefits Institute
Sonya Snedecor, Pharmerit
Cheryl Neslusan, Janssen Scientific Affairs
Rahul Dhanda, Neurocrine Biosciences, Inc.
Andrew Sperling, National Alliance on Mental Illness
Kevin Ronneberg, Health Partners
Jessica Kennedy, Mental Health America
Bruce Sherman, National Alliance of Health Purchaser Coalition
Patrick Gillard, AbbVie
Jennifer Bright, IVI
Erica deFur Malik, IVI
Richard Xie, IVI
Hanh Nguyen, IVI

The Major Depressive Disorder Advisory Group met January 11, 2021. The purpose of the meeting was to review the initial scoping documents for the major depressive disorder value assessment model. IVI and its research partners were seeking feedback from the Advisory Group on the rationale and considerations set forth by IVI's research partner, Pharmerit.

Meeting Highlights
IVI and Pharmerit aim to develop a flexible, rigorous, user-friendly, and open-source model that will serve the decision needs of diverse stakeholder groups, including payers, employers, researchers, and patients.

- Pharmerit presented the initial model scoping highlighting the following elements:
    - The initial model scope was developed based on literature review and input from the Advisory Group, with a particular emphasis on reflecting multiple perspectives.
        - Examples of flexibility include: variable model time horizon, customized model outputs of interests, use of different clinical outcome measures in defining health states

- Key takeaways
    - **Patient-centeredness** – the IVI-MDD model will seek to incorporate and reflect patient perspectives in the following specific ways:
        - Ensure the model structure and transitions are consistent with real-world patient experiences.
        - Leverage the findings from the PAVE study to (1) examine that the patient-prioritized elements are reflected in the model design, and (2) explore the adjustment of health state utilities based on estimated preference weights.
        - In the next few weeks, IVI may reach out to individual advisory group members (e.g., APA) with specific questions.
    - **Outcome measures following treatment** – MADRS and HAM-D were used to define treatment response in the initial recommendations based on the availability of clinical evidence and prior inputs from the AG.
        - IVI will continue to evaluate the feasibility of including additional measures such as PHQ-9 and other patient-reported outcomes.
    - **Treatment options** –IVI will work with the AG to evaluate the most relevant treatment options for specific patient groups and reflect this in the model design.
    - **Model Output** – instead of featuring one metric, the IVI-MDD model seeks to provide the flexibility to generate a set of traditional and novel model outputs.
        - We acknowledge that QALY has its limitations. However, including cost per QALY along with other measures will allow decision makers to compare and help evolve the science and practice of VA.
        - We will evaluate the feasibility and priority of other output measures proposed by the Advisory Group (e.g., cost per responder, NNT).
    - **Productivity –** we will evaluate the nuances of loss of productivity (e.g., absence due to illness, receiving treatment) in evaluating the productivity loss.
    - **Time to efficacy** - IVI will work with research partner to evaluate evidence on whether time to efficacy varies by treatment options.
    - **All-cause vs. MDD-specific medical costs** – the research teams will evaluate the feasibility of adding all-cause and MDD-specific costs, particularly for patients with comorbid conditions.
    - **Alternative decision-analytic framework** – the IVI-MDD model will include a module using multi-criteria decision analysis (MCDA) framework, in addition to the traditional cost-effectiveness analysis. Currently, we are forming a workgroup of MCDA experts that will advise the development of this module.

The Advisory Group will not meet in February. The next Advisory Group meeting will be part of the public comment period for the draft scoping document.

Chat Discussion from the Meeting

Jennifer Bright: So glad to have everyone here today. Please remember to use chat to ask any and all questions, share ideas etc. that we need to keep in mind. We will monitor to ensure any questions are addressed during the call, but the chat is your way to speak your mind. Thank you!

rahul dhanda: are you going to do a sensitivity analyses on the time horizon, 3 years, 10 years and lifetime ? What do you propose to use as denominators? QALYs, DALYs, Days without MDD ?

Richard Xie: Hi Rahul - yes the model will provide the flexibility to explore different time horizon. it will be covered in later parts of the presentation.

Cheryl Neslusan: what about PHQ-9 as an outcome measure (used in HEDIS)?

Patrick Gillard:The patient population selected will change the "bucket" of treatments that make clinical sense. Utility estimates do exist in the published literature for remission, response, etc.

rahul dhanda: costs: are they all cause; or disease specific?

rahul dhanda: I like the idea of Hedis--will the model incorporate quality measures, as described by HEDIS? Perhaps as denominators?

Benjamin Miller: With respect, HEDIS is a pretty low bar for quality. I realize it's like the easiest - but wondering if we could be more considerate of patient reported outcomes measures....

Andrew Sperling, National Alliance on Mental Illness: NAMI and many of our allies in the disability community have tremendous concerns with the use of QALYs in measuring outcomes.

Jessica Kennedy: Agree with Andrew. QALY is challenging for us.

Benjamin Miller: Agree with Andrew, too. We have trended to look at WALYs though that is still a developing science...

Jennifer Bright: Good discussion about measures to use - this will be important as we continue to shape this. Benjamin, if you have specific PROs you want to point us to (to ensure we capture in the literature review), please do.

Jennifer Bright: With regard to QALYs, please keep in mind that we do intend to model using both traditional approaches to CE analysis (ie QALY) as well as newer methods. This is to demonstrate differences in perspective and to demonstrate how this shows a more flexible

picture of value. We concur with the characterization that this is problematic, but also trying to evolve both the science and the practice.

Becky Yowell: APA is in the process of developing quality measures in the following areas: Measurement Based Care, Functioning, Recovery, Suicide. Tool chosen specific to Function is the WHODAS, Recovery is the RAS (recovery audit scale), and for Suicide it is the CSSRS. (ideas to start)

Becky Yowell: MBC measure is adaptable to any validated tool.

rahul dhanda: i would support the use of $/Qaly as there are thresholds that would establish whether the treatment is efficient to use in everyday practice. NNT is another measure to look at .

Brian Gifford: Productivity question 1: For workforce participation, is the intent to differentiate labor force participation from missed work due to absence or disability?

Brian Gifford: To clarify, I meant marginal absence due to illness, rather than absences to receive treatment. Potentially a fourth outcome, but should be easy to incorporate in a single lost work time measure.

rahul dhanda: it would be good to establish the efficiency of treatment for various subgroups. An overall evaluation is good, but more interesting otherwise, I think

Jessica Kennedy: there's a missing patient element of how they view the treatment is working

Jessica Kennedy: even if my PHQ9 score changes, if I feel crappy on my treatment for other reasons I may not like it

Patrick Gillard:Time to efficacy worth looking at if different among treatment options.

Jessica Kennedy: oh for sure it's complex

Julia Slejko: Very nice presentation of a very complex scenario. Will look forward to next steps with patient value elements.

Cheryl Neslusan: Thanks much for the presentation today - look forward to reading the draft protocol!