Multijurisdictional Contractor Advisory Committee (CAC) Meeting Pharmacogenomics Questions

All questions are related to psychiatric medications only. Answers will become part of the evidentiary record. While we prefer to use the highest quality evidence in writing coverage policy, we recognize that there may be gaps in the literature, and we are interested in expert opinion addressing these gaps. Please feel free to say that you are not comfortable answering or that you feel that the answer is beyond your area of expertise:

1. Please give a general background of how genetics related to the selection of medications or medication dosage?

2. Are there particular genes known to physiologically affect drug metabolism in humans?

3. Are there particular genes known to affect physiologically drug efficacy in humans via pharmacodynamics pathways?

4. Generally speaking, when does knowing the presence or absence of a genetic variant that affects pharmacokinetics or pharmacodynamics provide a physician with clinically actionable information? Is knowledge of lifestyle factors also necessary, or is genetic information sufficient?

5. Are there particular genes that are known to provide clinically actionable information in humans and that show reproducible improved clinical outcomes that are sustainable for the selection or dosing of psychiatric medications? Can you give information about the evidence underlying this?

6. For each of the genes that are known to provide clinically actionable information, what should be the minimum testing standards in terms of variants identified?

7. Is the evidence sufficient to conclude that large combinatorial pharmacogenomics panels (e.g. Geneight, IDGenetix, CNSDose, etc.) add something to medication selection above and beyond single gene testing? If so, in which populations, and with what strength of evidence?

8. In which kinds of circumstances would either single gene or combinatorial testing be used?

9. Do you have any other thoughts or information that you believe should be part of the evidentiary record in the development of a coverage policy?