CMS Registry Requirements and corresponding DS variables

Item	*CMS Variable*	DS/AD Variable
Provider/Patient Information:		
1	National Provider Identifier	Same
2	Medicare Beneficiary ID	Same
3	Contact Information (for Provider)	Same
Diagnosis:		
4	Clinical Diagnosis* (drop down menu) MCI due to AD, Mild AD Dementia	Same
5	Date of Clinical Diagnosis*	Same
One of these needs to be provided to confirm amyloid pathology:		
6	Amyloid Pet Scan* (drop down menu) Negative/Not performed/Positive	Same
7	CSF Test* (drop down menu) Negative/Not performed/Positive	Same
8	Other Amyloid Test* Negative/Not performed/Positive	Same
9	Other Information	
At least one cognitive test is required:		
10	MoCA Score	MoCA for DS with normal IQ; *specialty DS test for others*
11	Date of MoCA	
12	Other Cognitive Test (name, score & date)	Specialty DS test (DLD, Camdex-DS, NTG-EDSD, NADD battery)
At least one functional test is required:		
13	FAQ Score	Can use FAQ – but will not necessarily reflect dementia
14	Date of FAQ	
15	Other Functional Test (name, score & date)	Possibly use NTG-EDSD
Optional test information:		
13	Performed CDR (yes/no) (if yes, drop down menu for "information" on these categories: Memory, orientation, judgement and problem-solving, community affairs, home and hobbies, personal care – does not specify what is meant by "information")	Possibly use NTG-EDSD
Additional Required Information:		
14	Is patient on anticoagulation?* (yes/no)	Same
15	Is patient on antiplatelets?* (yes/no)	Same
16	Monoclonal antibody used (populates with only with Lecanemab)	Same
17	Is there evidence of significant ARIA-E?* (yes/no)	Same
18	Is there evidence of significant ARIA-H?* (yes/no)	Same
Closing items		
20	I am not a robot (Captcha)	Same
21	Submit	Same
*Not defined but assumed to be required; CDR: Clinical Dementia Rating; FAQ: Functional Assessment Questionnaire; MoCA: Montreal Cognitive Assessment		

Commentary by Expert Panel:

The Panelist's comments focused on the diagnosis and assessment of Down Syndrome-Associated Alzheimer's Disease (DSAD). Several key points were raised by the participants. First, the inclusion of amyloid pathology in the diagnostic process was highlighted as an important factor. It was acknowledged that extensive questionnaires are challenging to implement in primary practice due to time constraints and the need to address multiple co-occurring conditions. However, a set of specific questions for annual evaluations was proposed as a practical approach. Emphasizing the importance of ruling out other conditions and considering progressive changes in the pattern of decline, the participants agreed that confirming what DSAD is not may be more crucial than confirming the diagnosis itself. Additionally, the need for additional testing to confirm the presence of brain amyloid was suggested for considering new medications.

Regarding the assessment of DSAD progression, the participants recognized the ideal approach of comparing preclinical abilities but acknowledged the lack of standardized assessments prior to concern. They discussed the challenges of documenting decline from preclinical status and the need for compelling evidence to support periodic evaluations using tools like the NADD abbreviated battery. The participants suggested a diagnostic approach based on informant concern, presence of brain amyloid, ruling out other causes, and confirmation by the primary care provider. However, they acknowledged the regulatory concerns and the growing need for consensus on diagnostic practices.

The diagnostic process was described as relying considerably on the clinical judgment of PCPs. The importance of excluding comorbid conditions and the reliability issues in diagnosing mild AD/MCI in DS were acknowledged. Diagnostic tools such as DLD, NTG-EDSD, CAMDEX-DS, and instruments comparing past and current performance were highlighted. The participants agreed on the need for operational definition of "early DS-AD" and consensus on best practices. Specific performance criteria for diagnostic tests were discussed, with considerations for individuals with lower historical IQs.

In conclusion, the discussion highlighted the complex nature of DSAD diagnosis and assessment, encompassing amyloid pathology, clinical work-up, exclusion of differentials, and the need for consensus on diagnostic criteria and best practices. The participants acknowledged the challenges and limitations but provided insights into practical approaches and areas requiring further research and validation.

7/9/23