

QIBA PET-Amyloid Biomarker Committee

Friday, February 11, 2022, at 9 AM CT

Call Summary

Additional notes provided by Dr. Smith

In attendance:

Anne M. Smith, PhD (Co-chair)

Tammie Benzinger, MD, PhD

Norman Foster, MD

Adriaan Lammertsma, PhD

Nancy Obuchowski, PhD

Gudrun Zahlmann, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Smith

The following were discussed:

- Manuscript to be submitted to SNMMI's [The Journal of Nuclear Medicine](#) (JNM); target date of 2/18
- Dr. Foster discussed latest developments regarding drug development and immunotherapy for Alzheimer's disease and ongoing concerns regarding CMS decisions
- CMS decision for final coverage to be announced on April 11, 2022
- Imaging site feasibility questionnaires (for Technical Confirmation)
- ACR Registry of MR and PET patient images
- QIBA presentations at SNMMI annual meeting

Next steps

- Dr. Smith to recommend a PET Amyloid speaker for the QIBA session at the SNMMI annual meeting
- BC members to review latest manuscript changes in preparation for submission to *JNM*
 - Some additional technical justification to be added
 - Dr. Foster offered to help with formatting EndNote references
- Ms. Matthews in the process of incorporating Dr. Sunderland's comments re: questionnaire responses

Additional notes provided by Dr. Smith

1. Consolidated questionnaire
2. Manuscript being submitted to SNMMI – Update
3. Other topics – Headed by Norm Foster
4. 2/4 Immuno-therapies have been approved by FDA for consideration of accelerated approval
 - One has been approved (Aduhelm from Biogen)
 - Roche/Genentech have not applied for accelerated approval
 - Lily and Eisai may withdraw their bid for accelerated approval, and complete Phase 3 trials instead
 - All 4 companies used PET Amyloid imaging (baseline and treatment follow-up)
 - Can be used to decide when treatment should end (discontinue when amyloid at normal levels)
5. CMS Immuno-Therapy Coverage Decision Apr. 11, 2022
 - CED coverage only, will likely be unchanged
 - No end date for final review
6. CMS decided to not change National Coverage decision for Amyloid PET
 - SNMMI submitted a letter requesting that be re-opened, in context of immuno-therapy
 - Currently, one PET amyloid scan is covered by Medicare per lifetime for CED purposes
 - Lack of approval of PET Amyloid is holding the whole field back
 - Reversing this decision will be difficult, but should be tried
 - Reversing National Coverage may never have been done before
 - Our Manuscript could help with reversing decision – target next week for JNM submission
 - Some group may need to make a request
7. Movement (ACR) to create a patient registry to consolidate imaging database (MR and PET)
 - Uploading the different treatment's images to the database
 - Opportunity for our Profile to be used to standardize the PET Amyloid imaging
 - Work with SNMMI on this topic (SNMMI meeting has a 90 min QIBA timeslot, 30 min talk in Amyloid Profile?)
8. Amyloid PET not reimbursed yet in Europe

Action items (ongoing)

- Dr. Smith to provide speaker suggestions for PET Amyloid presentation at SNMMI to Dr. Zahlmann
- RSNA staff to prepare for the Technical Confirmation vote once co-chairs confirm documents are ready
- Drs. Wong and Smith to ask the SNMMI brain imaging council to consider providing an endorsement
- Consider contacting EANM neuroimaging committee
- BC may need to consider offering authorship to additional collaborators for the manuscript to more clearly emphasize that it is a QIBA product
- Dr. Lammertsma to share citations from Alzheimer's research
- Dr. Smith or Ms. Matthews to add a Profile note indicating that data are simulated
- Ms. Matthews to reformat the Profile checklist from Excel to Word
- Co-chairs to respond to Mr. O'Donnell's suggestions
- Ms. Matthews to list key highlights for the best opportunities for harmonization: recommendations requested
- Ms. Matthews and Dr. Foster to schedule a call with Dr. Koeppe to discuss the ADNI-QIBA gap analysis
 - Dr. Wong to be included
- Ms. Matthews to reach out to Dr. Seibyl regarding introduction to Invicro
- BC discussion on how to handle resistance to Profile requirements
- Produce an online questionnaire with scoring capability, modeled after FDG-PET BC

Next call – [March 11th](#) at 9 am CT