Certificate of Need Positron Emission Tomography (PET) Scanner Services Workgroup Meeting Notes

Thursday, February 25, 2021

9:30am – 11:30 A.M.

AGENDA

I. Call to Order **Chairperson Brandon Mancini, MD**

- Meeting called to order at 9:32 AM.

II. Overview of Workgroup Process **Brenda Rogers, MDHHS**

- PowerPoint presentation reviewing Michigan Certificate of Need processes and procedures and the overview of Informal Workgroup operations and recommendations process.

III. Review of Charges **Chairperson Brandon Mancini, MD**

- Review the oversight requirements to initiate mobile and fixed services (Charge #1).
- Review minimum volume requirement to convert to a fixed service (Charge #2).
- Review if specific requirements should be added to the PET standards for fixed novel whole-body PET/CT and PET/MR scanners located immediately adjacent to a modern cyclotron-equipped radiopharmacy (Charge #3).
- Consider any other technical changes from the Department, e.g., updates on modifications consistent with other CON review standards and the Michigan Public Health Code (Charge #4).

IV. Discussion and Prioritization of Charges **All**

- Charge #1:
    - Discussion/Feedback:
        - Are the services listed under Section 3, Part 1 still relevant today to approve a PET application? What is meaningful when considering PET? Consider no changes, adding specialties and/or other requirements, and/or eliminating some specialties and/or other requirements.
        - Extensive list of specialties/requirements. Concern that many community-based facilities participating in PET have a focus in oncology (and maybe recently cardiology), but a list with specialty niches less prevalent in community-based hospital settings may make requirements difficult to meet.

        - Written statements with small hospitals performing 100% of PETs for oncology populations. Current review standards require open heart surgery amongst other non-oncologic specialties. It can be difficult to get support from bigger institution. Possibly consider a modification to specify what services an institution is planning to use their PET scanners for?
        - MRI does not include such requirements. PET has novel applications coming, including drugs with targets in neurology, staging for prostate cancer, etc. Support removing some requirements to increase access. Need to examine what is required and remove barriers for community and rural settings.
        - Section 3, Part 2 allows the ability to partner with larger center(s). Most rural facilities/centers have the ability for such an arrangement. This limits access to those facilities doing high-level care. Consider modification of Section 3, Part 2 instead of dropping items from Section 3, Part 1.
        - Important to evaluate the access/availability across the state in rural versus metropolitan areas to understand the need for additional services. Review the CT Workgroup recommendations from recent past to see how it compares to PET and potentially use such information to create recommendations.
- Charge #2:
    - Discussion/Feedback:
        - State's PET Workgroup in 2010 increased the requirement from 1500 PET equivalents to 1700 PET equivalents. Despite continued building of PET program, 1700 PET equivalents has not been met over this 10-year period for a 600+ bed hospital with a robust oncology practice. Given the difficulty in increasing volume to 1700 PET equivalents over 10 years, it would be valuable to reassess this number, its relevance, and whether it needs to be modified.
        - Other providers sharing same mobile provider (i.e. on same service route) would like to increase volume, but all vying for hours/time on the unit, which holds back such growth.
        - There are large demands with additional desire to expand services, but current requirements limits the ability to increase volume.
        - In addition, the above-mentioned situation necessitates asking patients from distant locations to drive to a fixed unit. It also pushes scheduling further out with oncology/treatment plans delayed due to access to service issues.
        - Also, it depends on the size of the institution. There are some community hospitals with small oncology programs, performing 1-2 PET scans per week. Larger sites should have the ability to expand services.

        - This is critical work now. FDA approval and expansion of the use of PSMA will increase demand for PET scans and it is important to make decisions now to support this anticipated increase in demand.
        - Difficulty having patients traveling for Axumin and/or other specialty PET scans from rural areas to larger centers. There will likely be some increase in volume in rural areas. PSMA will lead to an increase in the number of patients undergoing PET scans given its incorporation into prostate cancer staging and the high incidence/prevalence of prostate cancer in the State of Michigan (and United States as a whole).
        - Support for Northern Michigan and rural communities. Hospital could benefit from fixed service with mobile outreach. Similar issues requiring smaller communities to be serviced on Sunday due to availability issues.
- Charge #3:
    - Discussion/Feedback:
        - This would facilitate placement of PET scanners adjacent to radiopharmacies.
        - Whole body PET/CT will allow 40x more sensitivity compared to conventional PET, with less radiation to patients (1/40th dose) or ability to scan much faster (40x).
        - Can serve pediatric population better (1% current of current pediatric patients undergo PET scans). It would reduce concerns about radiation dose and sedation requirements.
        - PSMA PET tracer is just one of the initial, exciting tracers. There are plans for theranostics moving forward.
        - Conventional PET scans scan from base of skull to mid-thigh. Whole body PETs will allow visualization of all micrometastases.
        - PET MR scanner needed for cardiology and neurology. This would offer soft tissue contrast that CT cannot offer.
        - PET/MR invented ~10 years ago in the U.S. It can serve patients in neurology/cardiology/oncology. There are ~50 PET MR scanners in the U.S. without a scanner located in Michigan. Stanford University with 5 PET/MR scanners and MD Anderson Cancer Center has ordered several this year. We have an opportunity for this workup group to have Michigan become a continued and progressive leader in medicine moving forward.
        - Current obstacle is that there is no number of PET equivalents and/or annual cases to scan because the current standards only apply to the use of FDG. Patients with needs other than FDG have a difficult time being served in Michigan.
        - Can current PET scanners become whole body scanners?
            - Whole body PET scanners are a brand-new technology with unique equipment. Higher sensitivity with 6x amount of detectors. Much more expensive piece of equipment.

- We can review the MRT CON for stereotactic radiosurgery (SRS)-only linear accelerators and compare/contrast to current PET scan standards verbiage/organization to assist with composing our recommendation(s).
- This pathway needs to be created to allow it to exist and have the opportunity to build from it. Support provided to finding a way for this to work
- Agree with this being a separate section of the review standards, comparable to the dedicated research fixed PET scanner (Section 7) and PET mammogram (Section 9) sections.
    - Arrangement with neighboring facilities could be included, as well as site initiation requirements.
- This represents a unique and fantastic boom to care.
- Not concerned about wide dissemination due to technology and cost requirements.
- This is a unique opportunity to serve as a laboratory and have specific applications taking advantage of motion sensitivity, creating novel tracers for MR and PET, etc. Excellent radiopharmacy support.
- The patients of the State of Michigan will benefit tremendously.
- We can modify the standard as appropriate in the future.
- Department would likely support separate section within the current review standards.

V. Review of Assignments & Next Steps All

- Subcommittees to be formed for all three major charges.
    - Several volunteers vocalized their commitment during the meeting and names have been recorded.
    - Others encouraged to email Brandon Mancini at bmancini@wmcc.org in the near future if they would like to volunteer on a subcommittee.
- Brandon Mancini will email subcommittee volunteers with goal-oriented metrics/assignments for next month's workgroup meeting.
- If appropriate, the workgroup's goal will be to have agreed upon recommendations for all charges by the May 20, 2021 meeting. Additional meetings to be utilized as needed moving forward.

VI. Adjourn

- Meeting adjourned at approximately 10:52 AM.

Future Meetings: March 25, 2021, April 22, 2021, May 20, 2021, & June 24, 2021