

1. Quality of Care – Quality of PET-CT Scan: The quality of a PET-CT scan is imperative to its interpretation. Accordingly, the Applicant will evaluate the number of scans that need to be repeated over the course of a week to ensure radiology technicians are performing appropriate scans. Given that the PET-CT equipment will only be available one day per week, the next opportunity for a scan would be seven days later.

Please explain a bit more, is the goal to differentiate and track repeat scans that were performed erroneously? Or is to verify findings s.a. false positives or "artifacts." Wouldn't Weds through the next Weds be 8 days?

The primary goal is to eliminate scans that do not satisfy the referrer's intent and therefore must be performed again. In a small percentage of cases, a discrepancy can occur between the referrer and the scan, which requires an additional scan. This can occur for a few reasons: 1) The patient's insurer and referrer are not in agreement on the procedure; 2) the referrer requests images outside of standard protocol; or 3) equipment failure rendering the scan insufficient. To help mitigate potential discrepancies, Shields uses eProtocol which allows the rendering provider to ask questions of the referrer prior to the exam to help ensure alignment between the desired outcome and actual outcome.

Measure: The number of repeat PET-CT scans performed on patients within a seven-day period (day of scan to next day of scan)

Projections: Baseline: 0% Year 1: 1% Year 2: 8% Year 3: 5%

We are not sure why these percentages are going up. If I understand, wouldn't the goal be 0% repeats?

The figures noted in the DoN application are incorrect. The figures should read:

Projections: Baseline: 0.04%, Year 1: 0.04%, Year 2: 0.04%, Year 3: 0.04%

These figures are derived from Shields PET/CT network data related to repeat scans. In 2020, the incidence of repeat scans is 0.04%. The Applicant believes that this figure will remain relatively stable during the first several years of operation.

Monitoring: PET-CT technologists will track the number of scans that are repeated and scheduled for the next scan day. Technologists will document each case and conduct a monthly comparison to total volume to meet or exceed the metric.

2. In order to demonstrate appropriate use of PET-CT the Holder will report on the effectiveness of ordering providers' use of the American College of Radiology (ACR) Clinical Decision Support Mechanism "ACR Select" for Adult imaging orders (or any subsequent CDSM). Holder shall provide, at minimum:

- a. Percent of ordering physicians using the mechanism (denominator = all ordering physicians; numerator – those using the CDSM)
- b. Data showing yearly changes in "low utility" or "marginal utility" advanced imaging orders; and
- c. The percentage of ordering providers' responses to alerts provided by ACR Select (or any subsequent CDSM)
- d. Annual analysis of these data, including any policy changes instituted as a result of these data.

The Centers for Medicare & Medicaid Services (CMS) announced it has delayed the mandate for referring providers to use appropriate use criteria (AUC) and clinical decision support (CDS) tools by one year. The testing period for physicians who order advanced imaging scans has been extended through the end of 2021.

Once the mandate for referring providers to use AUC goes into effect, Shields will have the capability of reporting:

- a.) The percent of ordering physicians using the mechanism
- b.) Data showing yearly changes in "low utility" or "marginal utility"
- c.) Percent of ordering providers' response to alerts provider by CDS tools
- d.) Analysis of data and policy changes instituted as a result of these data.

3 Conduct a critical value report* for PET-CTs. Holder shall report on the following:

- a. % of important finding alerts (IFAs) where critical value report was indicated
 - b. % of critical value reports radiologists performed over the total number of IFAs
- Any policy changes instituted as a result of increasing critical value reporting

PET is largely used as a staging tool. There is a known disease, particularly cancer, diagnosed primarily by tissue pathology (biopsy). PET's role is to evaluate the stage of the disease as guidance for treatment, then evaluate the effectiveness of treatment. Consequently, critical findings are low and would be communicated between the Radiologist and referring physician with guidance for further evaluation. Example, cancer patient with expected advanced disease. Possible tumor found in the brain which is a low resolution area for PET. Radiologist would suggest an MRI of the head to confirm. A formal reporting tool would be under-effective due to the role PET plays in patient disease management.