Introduction

HTA has selected positron emission tomography, alone or combined in one system with CT (PET) for Lymphoma to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input on all available evidence. HTA published the Draft Key Questions to gather input about the key questions and any additional evidence to be considered in the evidence review, and will review the public comments submitted and finalize the key questions. Key questions guide the development of the draft evidence report.

Despite varying levels of evidence supporting beneficial health outcomes, clinical use of PET in the evaluation, treatment, and monitoring of lymphoma appears to be growing. There are concerns about efficacy, safety, cost, and health impact of use of PET for lymphoma. Information about when PET for lymphoma is clinically indicated and what health outcomes it improves is needed.

At this phase, HTA is requesting public comments on the key questions. Key questions will direct the gathering, review, and summary of the evidence for the report. The HTA considers all public comments and we are particularly interested in comments that include information on whether the key questions will identify available evidence about the technology’s safety, efficacy, effectiveness, and cost effectiveness. Once the key questions are finalized, the vendor will search for evidence and compile a draft report. The draft report will then be published for review and public comment.

Key Questions

1. What is the evidence of accuracy of PET (alone or combined on one system with CT) imaging for lymphoma?
   - Describe sensitivity, specificity, and other key test characteristics in screening and initial diagnosis
   - Describe sensitivity, specificity, and other key test characteristics in staging/re-staging and surveillance.
   - Include comparators of MRI, CT, Gallium Scintigraphy, biopsy

2. What is the evidence of clinical effectiveness of PET imaging in patients with known or suspected lymphoma compared to CT and MRI when used as an adjunct to CT or MRI or Gallium Scintigraphy, including:
   - Reduced need for other tests
   - Planning or changing patient management (e.g. continuation of chemotherapy)
   - Improvement in quality of life
   - reductions in morbidity and mortality
   - improved patient outcomes with vs. without PET

3. What is the evidence that PET imaging in patients with known or suspected lymphoma has differential efficacy or safety issues in sub populations? Including consideration of:
   a. Patient age, gender, characteristics or evidence based patient selection criteria
b. Type of scanning machine and software, reader training, and other operational factors
   c. Provider type, setting or other provider characteristics
   d. Health care system type, including worker’s compensation, Medicaid, state employees

4. What is the evidence of PET for lymphoma safety profile?
   a. Adverse events type and frequency (mortality, major morbidity, other)

5. What is the evidence about the cost impact of PET for patients with known or suspected lymphoma? Including consideration of:
   a. Costs in short term
   b. Costs in long term
   c. Cost effectiveness

Technology Background
It is estimated that 74,000 US individuals will be diagnosed with lymphoma (about 65,500 non-Hodgkin lymphoma and 8,500 Hodgkin lymphoma). Successful treatment by complete remission of lymphoma, depending on stage, and 5 year survival rates are as high as 80 to 90%. Accurate information about diagnosis and staging is important for planning the most appropriate treatment strategy; as well assessing how a person is responding to treatment, and monitoring if the cancer has recurred. Physical symptoms; palpation; biopsy; MRI; CT; PET and PET/CT can used to assess patients. Positron emission tomography and PET/CT (collectively PET), are increasingly performed to inform restaging (assessment of treatment response), as well as diagnosis, staging, and monitoring of recurrence of cancer.

Technology:
PET produces a three-dimensional image of certain changes (biochemical processes) in the body by tracking where radioactive molecules (most commonly fluorodeoxyglucose or FDG) accumulate, which can indicate presence and extent of abnormal function associated with tumor tissue. PET/CT combines PET and a computed tomography in a single system so that images acquired from both devices can be taken sequentially in the same session and combined. The potential advantage of the functional imaging obtained by PET can be correlated with anatomical imaging obtained from CT.

PET has diffused rapidly, following several studies showed that PET or PET/CT used in Hodgkin lymphoma and an aggressive non-Hodgkin lymphoma at the end of front-line, salvage, or high-dose therapy provided accurate information about remaining cancer. It has since diffused to use in other lymphoma types and many stages of lymphoma diagnosis, treatment, and monitoring; guidelines for use are primarily based on expert consensus; and information about the evidence of timing of PET/CT; need for repeated scans and effect, compared to other assessment means, on use of invasive tests, therapeutic choices, and health outcomes is needed.