I. PURPOSE

The purpose of this policy is to provide general information applicable to the review and appropriateness of Image-Guided Radiation Therapy (IGRT).

II. DEFINITIONS

Image Guided Radiation Therapy (IGRT): This technique utilizes imaging technology to modify treatment delivery to account for changes in the position of the intended target. IGRT is used in conjunction with IMRT/VMAT for tumors that are located near or within critical structures and/or in tissue with inherent setup variation.

IGRT TECHNIQUES

A. Ultrasound (US) Guidance: This method uses Ultrasound Guidance for placement of radioactive beads or needles (brachytherapy) directly into the cancerous tissue.

B. Computed Tomography (CT) Guidance: This method requires the utilization of CT to place the field appropriately prior to each treatment. kV (kilo-voltage) or MV (mega-voltage) Cone-beam CT (CBCT) or tomotherapy are the approved devices.

C. Stereoscopic x-ray Guidance: This method requires the direct visualization of the designated target or localization through visualization of implanted fiducial markers. Matching to surgical clips in the treatment volume for post-operative cases is allowed in selected cases.

D. Continuous Localization Systems: These non-ionizing technologies, which are designed to localize the tumor, patient, or surrogate continuously, include the electromagnetic guidance system Calypso®, as well as the camera systems RadioCameras™ and AlignRT®.

E. Respiratory Motion Management (RMM): Methods used in the management of respiration motion in radiation oncology are as follows: 1. Motion-encompassing methods (slow CT scanning, inhale/exhale breath hold CT, four dimensional (4-D) CT/respiration correlated CT) 2. Respiratory gating methods (residual tumor motion within gating window, gating using an external radiation signal, gating using internal fiducial markers, gated IMRT/VMAT) 3. Breath-hold methods (deep-inspiration breath-hold (DIBH), active-breathing control (ABC), self-held breath-hold with/without respiratory monitoring, breath-hold in combination with IMRT/VMAT) 4. Forced shallow breathing (FSB) with abdominal compression 5. Real-time tumor tracking methods (direct tumor imaging, tumor location using implanted fiducial markers, tumor position prediction based on surrogate breathing signals, non-radiographic tumor tracking)

III. POLICY

Indications for approving a request for medical necessity of IGRT in approved IMRT/VMAT cases are:

1. Prostate Cancer
a. US guidance may be used daily for treatment of prostate cancer
b. Daily CT guidance may be used as a sole modality
c. Daily kV or MV CBCT imaging is permissible when treating the prostate only if fiducial markers have been placed in the prostate or prostate bed
d. In post-prostatectomy cases, when bony landmarks are being used to align the patient, IGRT is not medically necessary

2. **Head and Neck Cancer**
   a. Daily kV or MV imaging may be used when bone and soft tissue structures or surgical clips in the treatment volume can be successfully fused.

3. **Breast Cancer**
   a. IGRT is not authorized in the treatment of the whole breast. An exception can be made on a case-by-case basis for the use of RMM-deep breath inspiration hold to protect the heart
   b. For partial breast accelerated IMRT/VMAT with fiducial markers of fusible surgical clips, kV CBCT imaging is appropriate
   c. US daily of the breast for boost treatment is considered investigational

4. **Anal Cancer**
   a. CBCT is authorized daily

5. **Lung Cancer**
   a. CBCT is authorized daily when IMRT/VMAT is approved
   b. Daily kV imaging is authorized when fiducial markers or surgical clips in the treatment volume are present or when the tumor can be visualized and fused successfully on x-ray

6. **Pancreatic Cancer**
   a. CBCT is authorized daily when IMRT/VMAT is approved in a curative setting
   b. kV/MV imaging may be used in the curative setting when fiducial markers or surgical clips are present in the treatment volume

7. **Post-operative Endometrial and Cervix Cancer**
   a. IGRT will be authorized when there is concern about toxicity to the small bowel and CBCT will be utilized to verify avoidance of hotspots. KV/MV using fiducial markers or surgical clips in the treatment volume may also be used in approved cases

8. **All other IMRT/VMAT approved sites**
   a. For pre-operative (dose limited), definitive, post-operative cases with fiducials or surgical clips in the treatment volume in place, stereoscopic/electronic portal imaging device (EPID) may be used daily
   b. For pre-operative (dose limited), definitive, post-operative cases without fiducials or surgical clips in the treatment volume, stereoscopic imaging would not be considered helpful if the target volume could not be seen on kV imaging. In this situation, CT guidance may be more appropriate

9. **IGRT for 3D cases**
   a. IGRT is not considered medically necessary in conjunction with 3D conformal treatment.
Exceptions to this policy will be made on a case by case basis based on the following circumstances:

1. Close proximity to a previously treated region – IGRT may be indicated on a daily basis when fiducial markers or surgical clips in the treatment volume are present or when the spine needs to be accurately visualized and other landmark structures, such as bony anatomy or the airway, are not present within the portal image.

2. Small treatment volume within the chest or abdomen when the target volume is not in close proximity to a landmark structure such as bone or airway, making accurate set-up difficult with MV image only.

3. As per the 2015 ASTRO Radiation Oncology Coding Resource example of an “…extremely obese patient: morbidly obese patients with deep-seated tumors… may need daily IGRT for setup.” It is presumed that MV imaging may not be helpful, and IGRT imaging techniques may offer better definition of landmark structures including bone and soft tissue structures.

4. For curative 3D-CRT for prostate cancer for those fractions in which whole pelvis treatment is not being delivered CBCT may be beneficial.

5. All cases of lung cancer.

6. Any case including the spine where MV imaging is poor and acceptable landmarks cannot be identified.

7. Cases of esophageal and gastroesophageal junction cancers.

8. Pelvic cancers treated in the prone position with the use of a belly board.

9. In the adjuvant treatment of breast cancer only during the boost to the surgical or lumpectomy bed when using photons.

10. In cases of external beam-based accelerated partial breast irradiation.

11. In cases where deep inspiratory breath holding (DIBH) technique is being used to treat left sided breast cancer.

12. In the preoperative or postoperative treatment of sarcoma.

**IGRT for Brachytherapy Cases**

In brachytherapy cases, imaging is medically necessary to verify source position in all but the simplest of cases. The images may also be used to perform dosimetry calculations. Unique circumstances may require the use of IGRT with brachytherapy, such as gynecologic or breast cancers and will be reviewed on a case-by-case basis.

**Policy Limitations:**

IGRT is not medically necessary in the palliative setting.

**IV. PROCEDURE**

1. In order to review a request for medical necessity, the following items must be submitted for review:
   A. Physician history and physical including radiographic reports IE: MRI, CT and prior PET/CT scans
   B. Attending Radiation Oncologist Consult or Progress note
   C. Radiation treatment plan or completed CTR

**V. APPROVAL AUTHORITY**

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

http://www.redjournal.org/article/S0360-3016(09)03303-3/abstract
http://www.journals4free.com/link.jsp?url=10664147
http://jco.ascopubs.org/content/early/2015/02/03/JCO.2014.58.5828.full
http://www.redjournal.org/article/S0360-3016(11)03604-2/abstract