Coverage Summary

Radiologic Therapeutic Procedures

Policy Number: R-003  Products: UnitedHealthcare Medicare Advantage Plans  Original Approval Date: 04/02/2008

Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 08/15/2017

Related Medicare Advantage Policy Guidelines:

- Delivery of IMRT/SRS/SBRT
- Stereotactic Computer Assisted Volumetric and/or Navigational Procedure
- Tumor Treatment Field Therapy

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

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   5. Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)
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I. COVERAGE

Coverage Statement: Therapeutic radiologic procedures are covered when Medicare criteria are met.

Guidelines/Notes:
Therapeutic radiological services (inpatient or outpatient) used the treatment of disease, are covered when such services are determined to be reasonable and necessary. Examples include, but are not limited to:

1. Percutaneous Transluminal Coronary Interventions (Interventional Cardiology)
Medicare does not have a National Coverage Determination (NCD) for transluminal coronary interventions (interventional cardiology).

Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. For state-specific LCDs, refer to the LCD Availability Grid (Attachment A).

For coverage guidelines for states with no LCDs, refer to the Wisconsin Physicians Services LCD for Percutaneous Coronary Interventions (L34761). (IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)

Committee approval date: November 15, 2016

Accessed July 3, 2017

2. Proton Beam Therapy (PBT)
   - Medicare does not have a National Coverage Determination (NCD) for proton beam therapy.
   - Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. For state-specific LCDs, refer to the LCD Availability Grid (Attachment B).
   - For states with no LCDs, refer to the UnitedHealthcare Medical Policy for Proton Beam Radiation Therapy with individual consideration for following diagnoses:
     - Malignant lesions of the head and neck when the intent of treatment is to be curative
     - Pancreatic and adrenal tumors
     - Unresectable retroperitoneal sarcoma and extremity sarcoma
     - Cancers of the lung and upper abdominal/peri-diaphragmatic cancers
     - Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum
     - Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
     - Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
     - Prostate Cancer, non-metastatic

   (IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced guidelines.)

Committee approval date: November 15, 2016

Accessed July 3, 2017

3. Intensity Modulated Radiation Therapy (IMRT)
   - Medicare does not have a National Coverage Determination (NCD) for IMRT.
   - Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. For state-specific LCDs, refer to the LCD Availability Grid (Attachment C).
   - For states with no LCDs, refer to the UnitedHealthcare Medical Policy for Intensity-Modulated Radiation Therapy for coverage guidelines. (IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)

Committee approval date: November 15, 2016

Accessed July 3, 2017

4. Combined use of Proton Beam Therapy (PBT) and Intensity-Modulated Radiation
Therapy (IMRT)

- Medicare does not have a National Coverage Determination (NCD) for combined use of PBT and IMRT.
- Local Coverage Determinations (LCDs) do not exist at this time.
- For coverage guidelines, refer to the UnitedHealthcare Medical Policy for Proton Beam Radiation Therapy and UnitedHealthcare Medical Policy for Intensity-Modulated Radiation Therapy. (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policies.)
- Committee approval date: November 15, 2016
- Accessed December 29, 2016

5. Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)

- Medicare does not have a National Coverage Determination (NCD) for Stereotactic Radiosurgery/Stereotactic Body Radiation Therapy
- Local Coverage Determinations (LCDs) exist and compliance with these LCDs is required where applicable. For state-specific LCDs, refer to the LCD Availability Grid (Attachment D).
- For states with no LCDs, refer to the MCG™ Care Guidelines, 21st edition, 2017, for Stereotactic Radiosurgery ACG: A-0423 (AC) and Stereotactic Body Radiotherapy ACG: A-0694 (AC) for coverage guidelines or information regarding medical necessity.
- (IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)
- Committee approval date: March 21, 2017
- Accessed July 3, 2017

6. Local Hyperthermia

Local hyperthermia is covered when used in connection with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies. It is not covered when used alone or in connection with chemotherapy. See the NCD for Hyperthermia for Treatment of Cancer (110.1) (Accessed October 19, 2016)

7. Stereotactic Computer Assisted Volumetric and/or Navigational Procedure (CPT codes 20985 and 0398T)

- Medicare does not have an NCD for stereotactic computer assisted volumetric and/or navigational procedure.
- There is only one Medicare Administrative Contractor (MAC) with Local Coverage Determinations (LCDs) and compliance with these policies is required where applicable. For state-specific LCDs, refer to the LCD Availability Grid (Attachment E).
- For states with no LCDs, refer to the UnitedHealthcare Medical Policy for Omnibus Codes for coverage guidelines. (IMPORTANT NOTE: After checking the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)
- Committee approval date: November 15, 2016
- Accessed July 3, 2017

8. Tumor Treatment Field Therapy (TTFT) (A4555 and E0766)

- Medicare does not have an NCD for Tumor Treatment Field Therapy
II. DEFINITIONS

**Proton Beam Therapy (PBT):** Proton beam therapy is a radiation treatment modality that delivers high-dose radiation to a localized site. Protons, being particles instead of X-rays, slow down faster than photons. They deposit more energy as they slow down, culminating in a peak (called a Bragg peak). This allows the majority of radiation to be delivered to the target site with less scattering of radiation around and beyond to the adjacent normal tissues. *LCD for Proton Beam Therapy (L34634) (Accessed October 19, 2016)*

**Stereotactic Radiosurgery (SRS):** The adjective “Stereotactic” describes a procedure during which a target lesion is localized relative to a fixed three dimensional reference system, such as a rigid head frame (61800) affixed to a patient, fixed bony landmarks, a system of implanted fiducial markers, or other similar system. This type of localization procedure allows physicians to perform image-guided procedures with a high degree of anatomic accuracy and precision.

Stereotactic radiation therapy (SRT) couples this anatomic accuracy and reproducibility with very high doses of highly precise, externally generated, ionizing radiation, thereby maximizing the ablative effect on the target(s) while minimizing collateral damage to adjacent tissues. SRT requires computer-assisted, three-dimensional planning and delivery with stereotactic and convergent-beam technologies, including, but not limited to, multiple convergent cobalt sources (e.g., Gamma Knife®), protons, multiple, coplanar or non-coplanar photon arcs or angles (e.g. XKnife®), fixed photon arcs or image-directed robotic devices (e.g., CyberKnife®) that meet the criteria.

SRS is a distinct discipline that utilizes externally generated ionizing radiation in certain cases to inactivate or eradicate a defined target(s) in the head or spine without the need to make an incision. The target is defined by high-resolution stereotactic imaging. To assure quality of patient care the procedure involves a multidisciplinary team consisting of a neurosurgeon, radiation oncologist, and medical physicist. SRS typically is performed in a single session, using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic-guidance system, but can be performed in a limited number of sessions, up to a maximum of five. Technologies that are used to perform SRS include linear accelerators, particle beam accelerators, and multisource Cobalt 60 units. In order to enhance precision, various devices may incorporate robotics and real time imaging. *LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151). (Accessed October 19, 2016)*

**Stereotactic Body Radiation Therapy (SBRT):** A treatment that couples a high degree of anatomic targeting accuracy and reproducibility with very high doses of extremely precise, externally generated, ionizing radiation, thereby maximizing the cell-killing effect on the target(s) while minimizing radiation-related injury in adjacent normal tissues.

The adjective “stereotactic” describes a procedure during which a target lesion is localized relative to a known three dimensional reference system that allows for a high degree of anatomic accuracy and precision. Examples of devices used in SBRT for stereotactic guidance may include a body frame with external reference markers in which a patient is positioned securely, a system of implanted fiducial markers that can be visualized with low-energy (kV) x-rays, and CT imaging-based systems.
used to confirm the location of a tumor immediately prior to treatment.

All SBRT is performed with at least one form of image guidance to confirm proper patient positioning and tumor localization. To minimize intra-treatment tumor motion associated with respiration or other motion, some form of motion control or “gating” may be used.

SBRT may be fractionated (up to 5 fractions). Each fraction requires an identical degree of precision, localization and image guidance.

Since the goal of SBRT is to intensify the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame, any course of radiation treatment extending beyond five fractions is not considered SBRT and is not to be billed using these codes. *LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151).* (Accessed October 19, 2016)

**Transluminal Interventions:** Encompass balloon dilatation, a variety of atherectomy devices as well as approved stents for coronary placement. Complementing medical therapy and aortocoronary bypass, transluminal interventions have emerged as a third therapeutic option for the management of patients with chronic angina, acute coronary insufficiency and evolving myocardial infarction. *LCD for Percutaneous Coronary Intervention (L33623).* (Accessed October 19, 2016)

### III. REFERENCES

See above

### IV. REVISION HISTORY

**08/15/2017**

Re-review with the following update:

Guideline 8 [Tumor Treatment Field Therapy (A4555 and E0766)] – added new to coverage summary based from DME MAC LCD Tumor Treatment Field Therapy (TTFT) (L34823).

**03/21/2017**

Re-review with the following update:


**11/15/2016**

Annual review with the following updates:

Guideline 2 [Proton Beam Therapy (PBT)]

- Removed the following from the individual consideration (IC) diagnosis list:
  - Malignant lesions of the para nasal sinus, and other accessory sinuses
  - Left breast tumors
- Added the following to the IC diagnosis list:
  - Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum
  - Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
  - Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
  - Prostate Cancer, non-metastatic

Definitions:

Stereotactic Radiosurgery (SRS) - Replaced CMS reference from the LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34136) (Retired) to the LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)
Stereotactic Body Radiation Therapy (SBRT) - Replaced CMS reference from the LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34136) (Retired) to the LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151).

08/16/2016  Guideline 7 (Stereotactic Computer Assisted Volumetric and/or Navigational Procedure)
- Added the CPT codes 20985 and 0398T to the section title
- Changed default policy for states with no LCDs from the retired Noridian LCD for Stereotactic Computer Assisted Volumetric &/or Navigational Procedure (L35133) to the UnitedHealthcare Medical Policy for Omnibus Codes.

03/15/2016  Guideline 5 [Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)]

02/11/2016  Guideline 5 [Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)]
- Restored reference to “MCG™ Care Guidelines, 19th edition, 2015” (MCG™ Care Guidelines, 20th edition updates will not be implemented until April 1, 2016)

01/19/2016  Guideline 5 [Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)]

Guideline 7 (Stereotactic Computer Assisted Volumetric and/or Navigational Procedure)
- Added guideline with default for states with no LCDs to the Noridian LCD for Stereotactic Computer Assisted Volumetric &/or Navigational Procedure (L35133)(new to the policy)
- Updated reference link(s) of the applicable LCDs to reflect the new condensed LCD link(s).

11/17/2015  Annual review, no updates.

10/01/2015  Updated reference link(s) to the applicable Medicare Administrative Contractor (MAC) LCDs to reflect the new/condensed LCD ID numbering effective October 1, 2015.

03/24/2015  Updated Guideline 5 [Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)] - Changed default guideline for states with no LCDs from Noridian LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L32234) to MCG™ Care Guidelines, 19th edition, 2015, for Stereotactic Radiosurgery ACG: A-0423 (AC) and Stereotactic Body Radiotherapy ACG: A-0694 (AC) for coverage guidelines or information regarding medical necessity.
01/20/2015  Annual review with the following updates:

Guideline 1 [Percutaneous Transluminal Coronary Interventions (Interventional Cardiology)]
- Changed default guideline for states with no LCDs from *National Government Services LCD for Percutaneous Coronary Intervention (L28395)* to *Wisconsin Physicians LCD for Percutaneous Coronary Interventions (L34139)*.
- Added language to indicate:
  - Coverage guidelines of the available LCDs align; there is uniformity.
  - There is no applicable UnitedHealthcare Medical Policy available at the time.

Guideline 2 [Proton Beam Therapy (PBT)]
- Changed default guideline for states with no LCDs from *First Coast LCD for Proton Beam Therapy (L29263)* to *UnitedHealthcare Medical Policy titled Proton Beam Radiation Therapy* with individual consideration for the following diagnoses:
  - Malignant lesions of the head and neck when the intent of treatment is to be curative
  - Malignant lesions of the Para nasal sinus, and other accessory sinuses
  - Left breast tumors
  - Pancreatic and adrenal tumors
  - Unresectable retroperitoneal sarcoma and extremity sarcoma
  - Cancers of the lung and upper abdominal/peri-diaphragmatic cancers
- Added language to indicate:
  - Coverage guidelines of the available LCD do not align; there is no uniformity. The UnitedHealthcare Medical Policy guidelines do not align with the available LCDs.

Guideline 3 [Intensity Modulated Radiation Therapy (IMRT)]
- Added language to indicate:
  - Coverage guidelines of the available LCDs do not align; there is no uniformity. The UnitedHealthcare Medical Policy guidelines do not align with the available LCDs.

Guideline 5 (Conventional, Conformal and 3D Conformal External Beam Radiation Therapy)
- Removed guideline; only available LCD, i.e., LCD for Radiation Oncology: External Beam/Teletherapy (L24354) was retired; there is no applicable UnitedHealthcare Medical Policy available at this time.

Guideline 6 [Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)]
- Changed default guideline for states with no LCDs from *Palmetto LCD for Stereotactic Radiosurgery (SRS) (L28303)* and *Novitas LCD for Stereotactic Body Radiation Therapy (SBRT) (L30277)* to *Noridian LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L32234)*.
- Added language to indicate:
  - Indications for coverage within available LCDs vary. There is no applicable UnitedHealthcare Medical Policy available at this time.

03/11/2014  Guideline #3 (Intensity Modulated Radiation Therapy)
- Revised guidelines for states with no LCDs
- Replaced Wisconsin LCD for Radiation Oncology Including Intensity Modulated Radiation Therapy (IMRT) (L30316) to the UnitedHealthcare Medical Policy for Intensity-Modulated Radiation Therapy
08/20/2013  Annual review, no updates
12/17/2012  Guidelines #4 (Combined Use of Proton Beam Radiation Therapy and Intensity-Modulated Radiation Therapy) added
08/20/2012  • Annual review
            • Updated Guidelines #4 Conventional, Conformal and 3D Conformal External Beam Radiation Therapy to state that currently, there is only one Contractor with LCDs for this procedure with no change in coverage guidelines for states with no LCDs
12/15/2011  LCD Grids (Attachments A – E) were updated
06/30/2011  • Annual review
            • Guidelines #1 Percutaneous Transluminal Coronary Interventions was updated
            • Also updated to include Guidelines #4 Conventional, Conformal and 3D External Beam Radiation Therapy
04/11/2011  LCD Availability Grids (Attachments A, B and C) updated

V. ATTACHMENT(S)

Attachment A - LCD Availability Grid

**Interventional Cardiology/Percutaneous Transluminal Coronary Interventions**

CMS website accessed July 3, 2017

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
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<tr>
<td>L33623</td>
<td>Percutaneous Coronary Intervention</td>
<td>A and B MAC</td>
<td>National Government Services, Inc.</td>
<td>IL, MN, WI, CT, NY, ME, MA, NH, RI, VT</td>
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<td>L34761</td>
<td>Percutaneous Coronary Interventions</td>
<td>MAC - Part B</td>
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<td>L34761</td>
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End of Attachment A

Attachment B - LCD Availability Grid

**Proton Beam Therapy/Proton Beam Radiotherapy**

CMS website accessed July 3, 2017

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<tr>
<th>LCD ID</th>
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<tr>
<td>L33937</td>
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<td>MAC Part B</td>
<td>First Coast Service Options, Inc</td>
<td>FL, PR, VI</td>
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<tr>
<td>L34634</td>
<td>Proton Beam Therapy</td>
<td>MAC - Part B</td>
<td>Wisconsin Physicians Service Insurance Corporation</td>
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<tr>
<td>L34634</td>
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<tr>
<td>L35075</td>
<td>Proton Beam Therapy</td>
<td>A and B MAC</td>
<td>National Government Services, Inc.</td>
<td>IL, MN, WI</td>
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**Attachment B - LCD Availability Grid**

**Proton Beam Therapy/Proton Beam Radiotherapy**

CMS website accessed July 3, 2017

IMPORTANT NOTE: Use the applicable LCD based on member’s residence/place of service AND type of service.

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<th>LCD ID</th>
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End of Attachment B

**Attachment C - LCD Availability Grid**

**Intensity Modulated Radiation Therapy (IMRT)**

CMS website accessed July 3, 2017

IMPORTANT NOTE: Use the applicable LCD based on member’s residence/place of service AND type of service.

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<th>LCD ID</th>
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<tr>
<td>L34080</td>
<td><strong>Intensity Modulated Radiation Therapy (IMRT)</strong></td>
<td>MAC Part B</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<td>L34217</td>
<td><strong>Intensity Modulated Radiation Therapy (IMRT)</strong></td>
<td>MAC Part B</td>
<td>Noridian Healthcare Solutions, LLC</td>
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End of Attachment C

**Attachment D - LCD Availability Grid**

**Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)**

CMS website accessed July 3, 2017

IMPORTANT NOTE: Use the applicable LCD based on member’s residence/place of service AND type of service.

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<th>LCD ID</th>
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<td>L34283</td>
<td><strong>Radiology: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)</strong></td>
<td>A and B MAC</td>
<td>Cahaba Government Benefit Administrators®, LLC</td>
<td>AL, GA, TN</td>
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<td>Noridian Healthcare Solutions, LLC</td>
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<td>L33410</td>
<td><strong>Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)</strong></td>
<td>A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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End of Attachment D

**Attachment E - LCD Availability Grid**

**Stereotactic Computer Assisted Volumetric and/or Navigational Procedure**

CMS website accessed July 3, 2017

IMPORTANT NOTE: Use the applicable LCD based on member’s residence/place of service AND type of service.

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<td>A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
</tr>
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</table>
### Attachment E - LCD Availability Grid

**Stereotactic Computer Assisted Volumetric and/or Navigational Procedure**

- CMS website accessed July 3, 2017

**IMPORTANT NOTE:** Use the applicable LCD based on member’s residence/place of service AND type of service.

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<td>L33392</td>
<td>Category III CPT® Codes</td>
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<td>L35008</td>
<td>Non-Covered Services</td>
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<td>L35094</td>
<td>Services That Are Not Reasonable and Necessary</td>
<td>A and B MAC</td>
<td>Novitas Solutions, Inc.</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
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**End of Attachment E**

### Attachment F - LCD Availability Grid

**Tumor Treatment Field Therapy (A4555 and E0766)**

- CMS website accessed August 8, 2017

**IMPORTANT NOTE:** Use the applicable LCD based on member’s residence/place of service AND type of service.

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<td>Tumor Treatment Field Therapy (TTFT)</td>
<td>DME MAC</td>
<td>CGS Administrators, LLC</td>
<td>AL, AR, CO, FL, GA, LA, MS, NC, NM, OK, PR, SC, TN, TX, VA, VI, WY</td>
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<td>CGS Administrators, LLC</td>
<td>IL, IN, KY, MI, MN, OH, WI</td>
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<td>Noridian Healthcare Solutions, LLC</td>
<td>CT, DC, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT</td>
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