ASTRO Model Policies

INTENSITY MODULATED RADIATION THERAPY (IMRT)

This Model Policy[1] addresses coverage for Intensity Modulated Radiation Therapy (IMRT).

DESCRIPTION

Intensity Modulated Radiation Therapy (IMRT) is a technology for delivering highly conformal external beam radiation to a well-defined treatment volume with radiation beams whose intensity varies across the beam. IMRT is particularly useful for delivering a highly conformal radiation dose to targets positioned near sensitive normal tissues.

TREATMENT

IMRT Treatment Planning

IMRT treatment plans are tailored to the target volumes and are geometrically more accurate than conventional or three-dimensional conformal radiation therapy plans. IMRT planning defines the necessary field sizes, gantry angles and other beam characteristics needed to achieve the desired radiation dose distribution.

IMRT treatment planning (i.e., inverse treatment planning) is a multi-step process:

1. **Imaging:** Three-dimensional image acquisition of the target region by simulation employing CT, MR, PET scanners or similar image fusion technology is an essential prerequisite to IMRT treatment planning. If respiratory or other normal organ motion is expected to produce significant movement of the target region during radiotherapy delivery, the radiation oncologist may additionally elect to order multi-phasic treatment planning image sets to account for motion when rendering target volumes.

2. **Contouring:** Defining the target and avoidance structures is in itself a multi-step process:

   a. The radiation oncologist reviews the three-dimensional images and outlines the treatment target on each slice of the image set. The summation of these contours defines the Gross Tumor Volume (GTV). For multiple image sets, the physician may outline separate GTVs on each image set to account for the effect of normal organ motion upon target location and shape. Some patients may not have GTVs if they have had previous treatment with surgery or chemotherapy, in which case treatment planning will be based on CTVs as described below.

   b. The radiation oncologist draws a margin around the GTV to generate a Clinical Target Volume (CTV) which encompasses the areas at risk for microscopic disease (i.e., not visible on imaging studies). Other CTVs may be created based on the estimated volume of residual disease. For multiple image sets, the physician may draw this margin around an aggregate volume containing all image set GTVs to generate an organ-motion CTV, or Internal Target Volume (ITV).

1 ASTRO model policies were developed as a means to efficiently communicate what ASTRO believes to be correct coverage policies for radiation oncology services. The ASTRO Model Policies do not serve as clinical guidelines and they are subject to periodic review and revision without notice. The ASTRO Model Policies may be reproduced and distributed, without modification, for noncommercial purposes.

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c. To account for potential daily patient set-up variation and/or organ and patient motion, a final margin is then added to create a Planning Target Volume (PTV).

d. Nearby normal structures that could potentially be harmed by radiation (i.e., "organs at risk", or OARs) are also contoured.

3. **Radiation Dose Prescribing:** The radiation oncologist assigns specific dose requirements for the PTV which typically includes a prescribed dose that must be given to at least 90-95% of the PTV. This is often accompanied by a minimum acceptable point dose within the PTV and a constraint describing an acceptable range of dose homogeneity. Additionally, PTV dose requirements routinely include dose constraints for the OARs (e.g., upper limit of mean dose, maximum allowable point dose, and/or a critical volume of the OAR that must not receive a dose above a specified limit). A treatment plan that satisfies these requirements and constraints should maximize the potential for disease control and minimize the risk of radiation injury to normal tissue.

4. **Dosimetric Planning and Calculations:** The medical physicist or a supervised dosimetrist calculates a multiple static beam and/or modulated arc treatment plan to deliver the prescribed radiation dose to the PTV and simultaneously satisfy the normal tissue dose constraints by delivering significantly lower doses to nearby organs. Dose-volume-histograms are prepared for the PTV and OARs. Here, an arc is defined as a discrete complete or partial rotation of the linear accelerator gantry during which there is continuous motion of the multi-leaf collimator to deliver an optimized radiation dose distribution within the patient. The essential feature of an IMRT plan is that it describes the means to deliver treatment utilizing non-uniform beam intensities. Each radiation beam or arc is, in effect, a collection of numerous "beamlets," each with a different level of radiation intensity; the summation of these "beamlets" delivers the characteristic highly conformal IMRT dose distribution. The physicist and dosimetrist perform basic dose calculations on each of the modulated beams or arcs. These patient specific monitor unit computations verify through an independent second dose calculation method the accuracy of the calculations.

5. **Patient Specific Dose Verification:** The calculated beams or arcs are then delivered either to a phantom or a dosimetry measuring device to confirm that the intended dose distribution for the patient is physically verifiable and that the intensity modulated beams or arcs are technically feasible. Additional information can be found in the ASTRO QA White Paper (General Reference #13), which critically evaluates guidance and literature on the safe delivery of IMRT, with a primary focus on recommendations to prevent human error and methods to reduce or eliminate mistakes or machine malfunctions that can lead to catastrophic failures.

Documentation of all aspects of the treatment planning process is essential.

IMRT Treatment Delivery

The basic requirement for all forms of IMRT treatment delivery is that the technology must accurately produce the calculated dose distribution described by the IMRT plan. IMRT treatment delivery may be accomplished via various combinations of gantry motion, table motion, slice-by-slice treatment (tomotherapy) and multi-leaf collimator (MLC) or solid compensators to modulate the intensity of the radiation beams or arcs.

The highly conformal dose distribution produced by IMRT results in sharper spatial dose gradients than conventional or three-dimensional conformal radiation therapy. Consequently, small changes in patient position or target position within the body can cause significant changes in the dose delivered to the PTV and to the organs at risk; thus reproducible patient immobilization is required for precision IMRT. Imaging techniques such as stereoscopic kilovoltage or megavoltage X-ray, ultrasound, or cone beam or megavoltage CT scan (collectively referred to as Image Guided Radiation Therapy or IGRT) may be utilized to account for daily motion of the PTV to accurately deliver the treatment.

Documentation Requirements

Documentation in the patient's medical records must support:

1. The reasonable and necessary requirements as outlined under the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

2. The prescription which defines the goals and requirements of the treatment plan, including the specific dose constraints to the target and nearby critical structures.

3. A note of medical necessity for IMRT by the treating physician.

4. Signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV) and surrounding normal tissue.

5. The target verification methodology must include the following:
   a. Documentation of the clinical treatment volume (CTV) and the planning target volume (PTV).
   b. Documentation of immobilization and patient positioning.

6. Independent basic dose calculations of monitor units have been performed for each beam before the patient's first treatment.

7. Documentation of fluence distributions (re-computed and measured in a phantom or dosimetry measuring device) is required.

8. Documentation supporting identification of structures that traverse high-and low-dose regions created by respiration is indicated when billing for respiratory motion management simulation.

INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY

Indications For Coverage

As IMRT technology was introduced and the appropriate clinical applications were being established, earlier versions of this model policy identified specific disease sites for which IMRT was considered a standard option. The maturation and dissemination of IMRT capabilities with improved clinical outcomes has expanded to the point that a definitive list of "approved sites" driven solely by diagnosis codes (ICD-9 or ICD-10) is no longer sufficient. However, it is important to note that normal tissue dose volume histograms (DVHs) or dosimetry must be demonstrably improved with an IMRT plan to validate coverage. Therefore, coverage decisions must extend beyond ICD-9 and ICD-10 codes to incorporate additional considerations of clinical scenario and medical necessity with appropriate documentation. For some anatomical sites such as nasopharynx, oropharynx, hypopharynx, larynx (except for early true vocal cord cancer), prostate, anus and central nervous system, IMRT should be considered standard of care, but for other sites, documentation of benefit is required.

IMRT is considered reasonable and medically necessary in instances where sparing the surrounding normal tissue is of added clinical benefit to the patient. Examples of reasons why IMRT might be advantageous include the following:

1. The target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s).

2. A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose "hotspot" within the treated volume to avoid excessive early or late normal tissue toxicity.

3. A non-IMRT technique would substantially increase the probability of clinically meaningful normal tissue toxicity.

4. The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

IMRT offers advantages as well as added complexity over conventional or three-dimensional conformal radiation therapy. Before applying IMRT techniques, a comprehensive understanding of the benefits and consequences is required. In addition to satisfying at least one of the four selection criteria noted above, the radiation oncologist's decision to employ IMRT requires an informed assessment of benefits and risks including:

- Determination of patient suitability for IMRT allowing for reproducible treatment delivery.
- Adequate definition of the target volumes and organs at risk.
- Equipment capability, including ability to account for organ motion when a relevant factor.
- Physician and staff training.
- Adequate quality assurance procedures.

On the basis of the above conditions demonstrating medical necessity, disease sites that frequently support the use of IMRT include the following:

- Primary, metastatic or benign tumors of the central nervous system including the brain, brain stem and spinal cord.
- Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated.
- Primary, metastatic, benign or recurrent head and neck malignancies including, but not limited to those involving:
    - Orbits,
    - Sinuses,
    - Skull base,
    - Aero-digestive tract, and
    - Salivary glands.
- Thoracic malignancies.
- Abdominal malignancies when dose constraints to small bowel or other normal tissue are exceeded and prevent administration of a therapeutic dose.
- Pelvic malignancies, including prostatic, gynecologic and anal carcinomas.
- Other pelvic or retroperitoneal malignancies.

The final determination of the appropriateness and medical necessity for IMRT resides with the treating radiation oncologist who should document the justification for IMRT for each patient.

ICD-9-CM and ICD-10-CM Codes that may be Associated with Medical Necessity

Note: Diagnosis codes are based on the current ICD-9-CM and ICD-10-CM codes that are effective at the time of the Model Policy publication. Any updates to ICD-9-CM or ICD-10-CM codes will be reviewed by ASTRO, and coverage should not be presumed until the results of such review have been published/posted. These ICD diagnosis codes may support medical necessity under this Model Policy.

System	Site	ICD-9 Codes	ICD-10 Codes
Head and Neck	Lip	140.0 - 140.9	C00.0 - C00.9
	Tongue	141.0 - 141.9	C01 - C02.9
	Major salivary glands	142.0 - 142.9	C07 - C08.9
	Gum	143.0 - 143.9	C03.0 - C03.9
	Floor of mouth	144.0 - 144.9	C04.0 - C04.9
	Other parts of the mouth	145.0 - 145.9	C05.0 - C06.9
	Oropharynx	146.0 - 146.9	C09.0 - C10.9
	Nasopharynx	147.0 - 147.9	C11.0 - C11.9
	Hypopharynx	148.0 - 148.9	C12 - C13.9
	Nasal cavities, middle ear and accessory sinuses	160.0 - 160.9	C30.0 - C31.9
	Larynx	161.0 - 161.9	C32.0 - C32.9
Digestive Organs and Peritoneum	Esophagus	150.0 - 150.9	C15.3 - C15.9
	Stomach	151.0 - 151.9	C16.0 - C16.9
	Small intestine	152.0 - 152.9	C17.0 - C17.9
	Colon	153.0 - 153.9	C18.0 - C18.9
	Rectum, rectosigmoid, anus	154.0 - 154.8	C19 - C21.8
	Liver, intrahepatic bile ducts	155.0 - 155.2	C22.0 - C22.9
	Gallbladder, extrahepatic bile ducts	156.0 - 156.9	C23 - C24.9
	Pancreas	157.0 - 157.9	C25.0 - C25.9
	Retroperitoneum, peritoneum	158.0 - 158.9	C45.1 C48.0 - C48.8
Respiratory and Intrathoracic Organs	Trachea, bronchus and lung	162.0 - 162.9	C33 - C34.92
	Pleura	163.0 - 163.9	C38.4 C45.0
	Thymus, heart and mediastinum	164.0 - 164.9	C37 - C38.8 C45.2

System	Site	ICD-9 Codes	ICD-10 Codes
Bone, connective tissue and skin	Bone	170.0 - 170.9	C40.00 - C41.9
	Connective and other soft tissue	171.0 - 171.9	C47.0 - C49.9
	Skin	172.0 - 173.99	C43.0 - C44.99 D03.0 - D03.9
	Kaposi's sarcoma	176.0 - 176.9	C46.0- C46.9
	Merkel cell carcinoma	209.31 - 209.75	C4A.0 - C4A.9 D3A.00 - D3A.8 C7B.00 - C7B.1
Breast	Female breast	174.0 - 174.9 233.0	C50.011 - C50.019 C50.111 - C50.119 C50.211 - C50.219 C50.311 - C50.319 C50.411 - C50.419 C50.511 - C50.519 C50.611 - C50.619 C50.811 - C50.819 C50.911 - C50.919 D05.00 - D05.92
	Male breast	175.0 - 175.9	C50.021 - C50.029 C50.121 - C50.129 C50.221 - C50.229 C50.321 - C50.329 C50.421 - C50.429 C50.521 - C50.529 C50.621 - C50.629 C50.821 - C50.829 C50.921 - C50.929
Genitourinary organs	Cervix	180.0 - 180.9	C53.0 - C53.9
	Uterus	179 182.0 - 182.8	C55 C54.0 - C54.9
	Ovary and adnexa	183.0 - 183.9	C56.1 - C57.4
	Other female genital organs	184.0 - 184.9	C51.0 - C52 C57.7 - C57.9
	Prostate	185	C61
	Testis	186.0 - 186.9	C62.00 - C62.90
	Penis and other male genital organs	187.1 - 187.9	C60.0 - C60.9 C63.00 - C63.9
	Bladder	188.0 - 188.9	C67.0 - C67.9
	Kidney	189.0 - 189.9	C64.1 - C66.9 C68.0 - C68.9

System	Site	ICD-9 Codes	ICD-10 Codes
Other sites	Eye	190.0 - 190.9	C69.00 - C69.92
	Brain, other parts of nervous system	191.0 - 192.9	C70.0 - C72.9
	Endocrine glands	193 194.0 - 194.9	C73 C74.00 - C75.9
	Benign neoplasms of brain, cranial nerves and meninges	225.0 - 225.2	D32.0 - D33.3
	Benign neoplasms of pituitary, pineal, aortic body and other paraganglia	227.3 - 227.6	D35.2 - D35.6
Malignant neoplasm of other and ill-defined sites	Various regions	195.0 - 195.8	C76.0 - C76.8 C45.7
Secondary and unspecified malignant neoplasm of lymph nodes	Lymph node metastases	196.0 - 196.9	C77.0 - C77.9
Secondary malignant neoplasm of respiratory, digestive and other specified sites	Metastatic disease other than lymph node metastases	197.0 - 199.1	C78.00 - C80.1 C45.9
Lymphatic and hematopoietic tissue	Non-Hodgkin's lymphoma	200.00 - 200.88 202.00 - 202.98	C82.00 - C86.6 C91.40 - C91.42 C96.A C96.0 - C96.9 C96.Z
	Hodgkin's lymphoma	201.00 - 201.98	C81.00 - C81.99
	Multiple myeloma	203.00	C90.00
Reirradiation	Various regions	990*	T66.XXXA*

*ICD-9-CM 990 or ICD-10-CM T66.XXXA (Effects of Radiation, Unspecified) may only be used where prior radiation therapy to the site is the governing factor necessitating IMRT in lieu of other radiotherapy. An ICD diagnosis code for the anatomic diagnosis must also be used.

Limitations of Coverage

IMRT is not considered reasonable and medically necessary unless at least one of the criteria listed in the "Indications of Coverage" section of this policy is present.

Clinical scenarios that would not typically support the use of IMRT include:

1. Where IMRT does not offer an advantage over conventional or three-dimensional conformal radiation therapy techniques that deliver good clinical outcomes and low toxicity.

2. Clinical urgency, such as spinal cord compression, superior vena cava syndrome or airway obstruction.

3. Palliative treatment of metastatic disease where the prescribed dose does not approach normal tissue tolerances.

4. Inability to accommodate for organ motion, such as for a mobile lung tumor.

5. Inability of the patient to cooperate and tolerate immobilization to permit accurate and reproducible dose delivery.

PHYSICIANS' CURRENT PROCEDURAL TERMINOLOGY (CPT®)/HCPCS

Note: CPT is a trademark of the American Medical Association (AMA)

CPT®/HCPCS codes

CPT Code for IMRT Treatment Planning

77301	Intensity Modulated Radiation Therapy (IMRT) plan, including dose-volume histograms for target and critical structure partial tolerance specifications. *This code is typically reported only once per course of IMRT.*
+77293	Respiratory motion management simulation (List separately in addition to code for primary procedure). *This is an add-on code and cannot be billed on its own. It should be billed with either CPT code 77295 or 77301.*

CPT Code for Collimator-based IMRT Treatment Delivery

77418	Intensity Modulated Radiation Therapy (IMRT) delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session *Use with dynamic multileaf collimators. Do not use for compensator-based treatment delivery; report using 0073T instead.*

CPT Code for Compensator-based IMRT Treatment Delivery

0073T	Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session *This code is a temporary CPT Category III code that should be used for tracking purposes.*

Medical Radiation Physics, Dosimetry and Treatment Devices

Basic Radiation Dosimetry

Basic radiation dosimetry is a separate and distinct service from IMRT planning and should be reported accordingly. The radiation dose delivered by each IMRT beam must be individually calculated and verified before the course of radiation treatment begins. Thus, multiple basic dosimetry calculations (up to 10) are typically performed and reported on a single day. Supporting documentation should accompany a claim for more than ten (10) calculations on a single day.

CPT® Code for IMRT Dosimetry

77300	Basic radiation dosimetry calculation central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician *This code can generally be billed once for each IMRT beam or arc up to a limit of ten. This code is used to report dosimetry calculations that arrive at the relationship between monitor units (or time) and dose, and the physician's verification, review and approval. The documentation should contain the independent check of each field, separate from the computer-generated IMRT plan.*

Treatment Devices

There are several categories of treatment devices used in conjunction with the delivery of IMRT radiotherapy. Immobilization treatment devices are commonly employed to ensure that the beam is accurately on target. In addition, the radiation oncologist is responsible for the design of treatment devices that define the beam geometry. The beam or arc aperture, the dose constraints per beam, the couch and gantry angles for each beam position or arc start/stop location, and the coverage requirements all must be evaluated in order to guide the generation of the multi-leaf collimator (MLC) segments. CPT® code 77338 was established to report multileaf collimator (MLC) design and construction for IMRT. It captures the physician work associated with design and fabrication of the device, the practice expense associated with staff (physicists and dosimetrists) and the equipment used to design, analyze and fabricate the device. While 77334 was previously billed once for each gantry angle, 77338 is billed only once per IMRT plan. There is no separate accounting for gantry angles or other beam arrangements. CPT code 77334 may be used in the IMRT process of care to report the immobilization device constructed at time of the simulation. Additional IMRT plans during a course of care merit additional reporting of 77338.

CPT Codes for IMRT Treatment Devices

77332	Treatment devices, design and construction; simple *Simple treatment devices include simple multi-use shaped blocks, bolus and passive, multiuse devices.*
77333	Treatment devices, design and construction; intermediate *Intermediate treatment devices include pre-cast or pre-made standard-shaped blocks, stents, and special bolus and bite blocks.*
77334	Treatment devices, design and construction; complex *Complex treatment devices include custom-fabricated cast blocks, immbolization devices, wedges, compensators and eye shields.*
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan *Report once per IMRT plan.*

Image-Guided Radiation Therapy

Image Guided Radiation Therapy (IGRT) utilizes imaging technology to modify treatment delivery to account for changes in the position of the intended target. IGRT is indicated for use in conjunction with IMRT for patients whose tumors are located near or within critical structures and/or in tissue with inherent setup variation. Thus, although IGRT is a distinct service, it may be used and documented along with IMRT treatment delivery (77418) when necessary. This service must be performed by a radiation oncologist, medical physicist or trained radiation therapist under the direct supervision of the radiation oncologist.

CPT® Codes for IGRT

76950	Ultrasonic guidance for placement of radiation therapy fields *Used with ultrasound-based 2 and 3D systems.*
77014	Computed tomography guidance for placement of radiation fields *Used with CT-based systems (i.e., integrated cone beam CT, CT/linear accelerator on rails, tomotherapy).*
77421	Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy *Used with stereoscopic X-ray-based systems (i.e., kV X-rays or MV X-rays: EPID (electronic portal imaging device) with fiducial markers).*
0197T	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (eg. 3D positional tracking, gating, and 3D surface tracking), each fraction of treatment *Used with implanted radiofrequency transponders and for 3D Surface tracking.*

ADDITIONAL INFORMATION

Coding Guidelines

The following CPT® codes are components of IMRT planning (CPT code 77301) and therefore **should not** be separately coded or billed on the same day of service as 77301. They may, however, be billed as needed, for medically necessary simulation and treatment planning during the course of IMRT treatment (i.e. with code 77418).

CPT® Code	CPT Code Descriptor	Criteria for Level
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation	The work of 3D image reconstruction is part of the process of care of 3D treatment planning and should not be reported using CPT codes 76376 or 76377
77014	Computed tomography guidance for placement of radiation therapy fields	IGRT-specific guidelines: Used with CT-based systems (i.e., integrated cone beam CT, CT/linear accelerator on rails, tomotherapy).

77295	Three-dimensional radiotherapy plan, including dose-volume histograms	One or more of the following exists: • Volume of interest lies in close proximity to normal structures that must be protected. • Volume of interest can only be defined by MRI or CT. • Multiple or conformal portals are necessary to cover the volume of interest with close margins to protect immediately adjacent structures. • Beam's eye view of multiple portals must be established for conformal treatment delivery. • An immediately adjacent area has been irradiated, and abutting portals must be established with high precision. • Three-dimensional reconstruction of the tumor volume, and the critical structure volume in brachytherapy cases, is used to develop dose-volume histograms for the tumor and critical structures.
77331	Special dosimetry (eg, TLD, microdosimetry) (specify), only when prescribed by the treating physician	Explanation of medical necessity may be required.

The following list of codes **should also not** be reported on the same date of service as IMRT planning (77301). They may, however, correctly be used, as needed, for medically necessary simulation and treatment planning during the course of IMRT treatment (i.e. with code 77418).

CPT® Code	**CPT Code Descriptor**	**Criteria for Level**
77280	Therapeutic radiology simulation-aided field setting, simple	Single treatment area
77285	Therapeutic radiology simulation-aided field setting, intermediate	Two separate treatment areas

77290	Therapeutic radiology simulation-aided field setting, complex	Any one of these factors present:
		• Three or more treatment areas
		• Any number of treatment areas if any of the following are involved:
		    • Particle
		    • Rotation or arc therapy
		    • Complex blocking
		    • Custom shielding blocks
		    • Brachytherapy simulation
		    • Hyperthermia probe verification
		    • Any use of contrast materials

77305	Teletherapy, isodose plan (whether hand or computer calculated); simple	One or two parallel opposed unmodified ports directed to a single area of interest.
77310	Teletherapy, isodose plan (whether hand or computer calculated); intermediate	Three or more treatment ports directed to a single area of interest.
77315	Teletherapy, isodose plan (whether hand or computer calculated); complex	Mantle or inverted Y, tangential ports, the use of wedges, compensators, complex blocking, rotational beam or special beam considerations.

REFERENCES

The medical literature regarding Intensity Modulated Radiation Therapy is extensive. The following list comprises a compliation of selected peer reviewed publications from the last 10 years reporting clinical outcomes in patients treated with IMRT, organized by disease site.

General

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