Diagnostic Procedures & Clinical Modalities across Subspecialties

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Disclaimer

Contents and opinions expressed in this presentation do not necessarily represent Blue Shield of California policies or view.

Disclosure

- No conflict of interest
- No financial interest
- Nothing to disclose

Objectives

- Offer understandable description and clinical justification (or lack of) for utilization of medical-surgical procedures & technologies.
- Clinical coding examples with specific CPT, HCPCS, ICD-9, DRG or APC codes for health care investigators, with explanation of clinical or payment logic/rationale.

Assumptions

- Working knowledge of coding, billing, claims processing and correct coding edits.
  - NCCI edits (Column I/Column II, MUE, ME)
  - Global Surgery edits
  - Maximum units edits
  - Duplicate claims edits
  - Place of service reduction
  - Multiple-imaging reduction
  - Multiple-surgery reduction

Assumptions

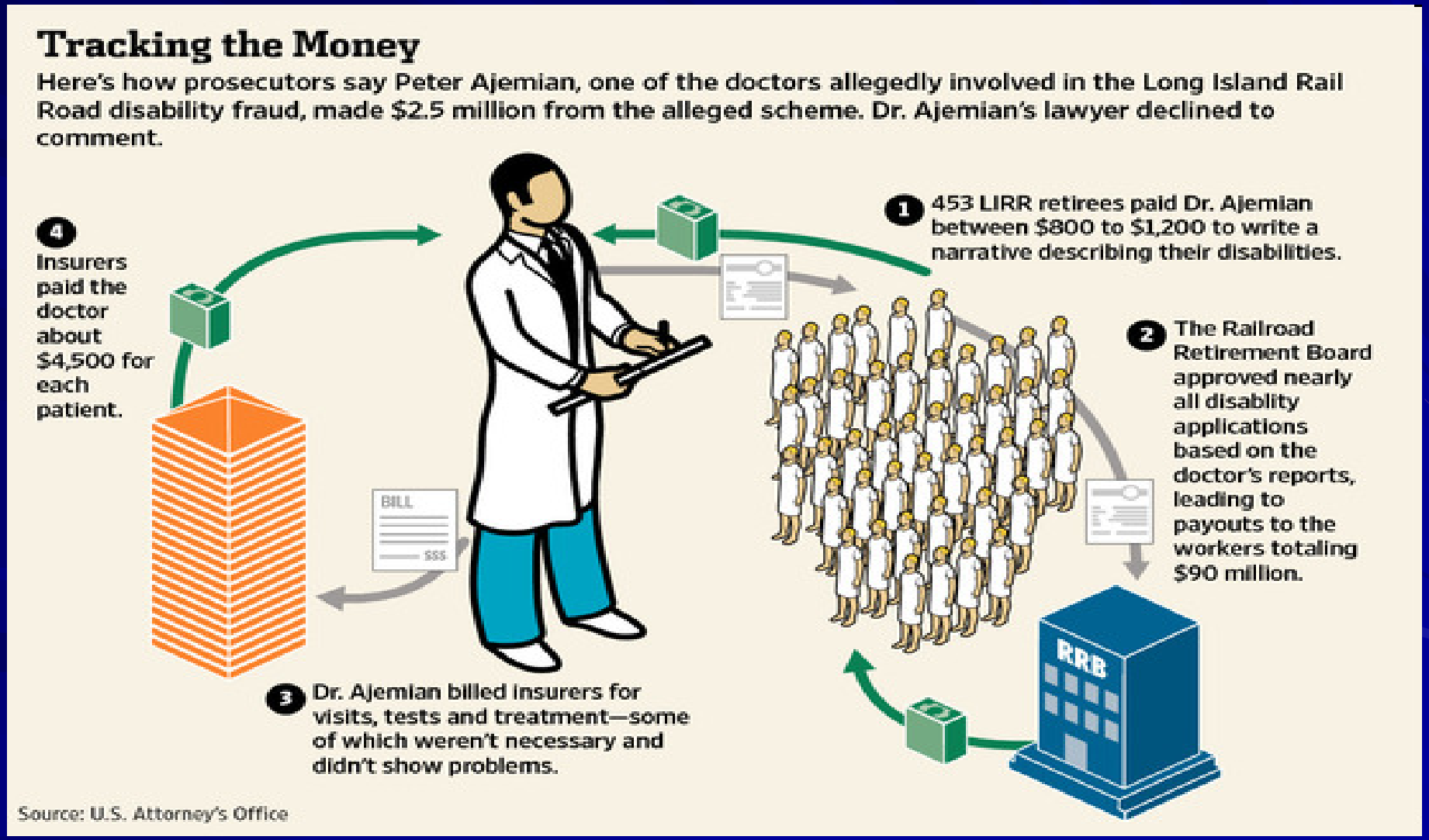
- Modifiers
- TC / modifier 26
- Scope of licensure
- Unbundling-rebundling edits
- Procedure-Dx edits
- Frequency edits
- Split claims
- DME, HHS, and customized edits, etc, etc.

- Interactive: Comments and/or questions from audience.
- Ø Chiro / Ø Podiatry / Ø Rx

Notorious Healthcare Fraud Schemes

- Rent-a-Patient schemes
  - Notorious SoCal hyperhidrosis case, 2007
  - Two types: conspiracy vs. unsuspecting
- Pill Mill schemes - IVIG / Factor VIII
  - Pharmacy Fraud. Recruit for expensive IVIG / Factor VIII; ↑ dosing
  - Drug middlemen resale of expensive Rx or narcotics
- Hit-&-Run / Drop Box schemes
  - Drop box (mail receiving outlets) rental + phony clinics
  - "Shock & Awe" massive billing / quick strike and retreat (disappear/mutate)
- 3rd Party Billing schemes
  - Billing through Medicare FI and/or Carrier – difficult to detect due to sheer volume and complexity
  - Generate computerized claims of recruits and submit to TPB
  - Physician Mgmt Co./Broker submitting extra claims unbeknownst to providers
- DME schemes
  - Billing for excessive or useless items, using high RVU codes

Disability Pension Scam



Disability Pension Scam

- ***WSJ*** (10/28/11): Long running scheme to defraud LIRR up to $1 billion
  - Fed prosecutors charged 11 people, including doctors & retirees, with organizing the crime.
  - Hundreds of LIRR employees to retire at age 50 with combined pension & disability payments
  - New York Times reported in 2008 that nearly every career LIRR employee was declared disabled by the Railroad Retirement Board.

Disability Pension Scam

- **Disability**: Severe pain when gripping and using simple hand tools and pain in knees, shoulders and back from bending or crouching
  Prosecutors say: Defendant signed in to play golf at a course 140 times over nine months in 2008.
- **Disability**: Activities such as walking and standing cause 'disabling pain' and stairs are 'very difficult.'
  Prosecutors say: Defendant was seen vigorously exercising at a gym for more than two consecutive hours, including a step-aerobics class.
- **Disability**: 'Disabling pain in back, shoulder & legs'
  Prosecutors say: Defendant completed a 400-mile bike tour in 2009.

Source: criminal complaint

Overutilization?

New York Times – November 14, 2011

- Doctors who earn money for cardiac stress testing are much more likely to prescribe the tests than those who don't, a new study has found.
- Researchers at Duke University studied data on 17,847 patients nationwide who had cardiac bypass surgery or coronary angioplasty, checking to see how often doctors prescribed nuclear stress tests and echocardiograms later than 90 days after discharge. Their results appeared Wednesday in The Journal of the American Medical Association.

Emerging Technologies

- TAVI / TMVI / TPVI
- Ultrafast EB CT / Helical-Spiral CT
- Gene Testing & “Companion Diagnostics”
- HIFU
- Bronchial Thermoplasty
- Proton/Particle Beam – *Monarch Still River & MIT Plasma Science Fusion Center*
- Tablet US

Emerging Technologies

- PROSE
- *SEDASYS™ CAPS System*
- *AngioSculpt Scoring Balloon Catheter*
- *HearTwave II MTWA Testing*
- *Balloon Sinuplasty*
- BrainLAB Novalis
- Biplane Angiography
- *Breast Tomosynthesis*
- *Double Balloon Enteroscopy*
- Niobe Navigation System

Emerging Technologies

- SilverHawk Plaque Excision
- Siemens ONCOR
- *Magnetoencephalography-Magnetic Source Imaging*
- *Coil Embolization - Aneurysm Coiling*
- TomoTherapy Hi-Art System
- Dual Source CT
- 3T MRI
- *Cell-Saver*

Emerging Technologies

- da Vinci Robotic Surgery System
- *IGRT – IMRT*
- Mammosite
- *Stereotactic RadioSurgery/SBRT Systems*
  - Varian LINAC Trilogy
  - Elekta GammaKnife PERFEXION
  - Accuray CyberKnife
  - Elekta Synergy/Synergy-SR
  - Proton Beam
- *CT Colonography (Virtual Colonoscopy)*

Emerging Technologies

- *MERCI Retrieval System*
- Wingspan Stent
- Percutaneous PFO Closure/Balloon Valvuloplasty
- PillCam Capsule Endoscopy
- Fusion Scan
- Artificial Disc
- *X-Stop Interspinous Process Spacer*
- *Kyphoplasty*
- 3D/4D Ultrasound
- FeNO

Emerging Technologies

- Genetic/Molecular Biologic Diagnostics
  - ApoE 4
  - Achrondroplasia (FGFR3)
  - Albinism
  - Alpha thalassemia (alpha globin)
  - Angelman syndrome (GABRA, SNRPN)
  - BrCa1/BrCa2
  - Beta thalassemia (beta globin)
  - Canavan disease (ASPA-aspartoacylase A)

Genetic & Molecular Biologic Diagnostics

- Charcot-Marie Tooth disease (PMP-22)
- Classical lissencephaly
- Crouzon syndrome (FGFR2, FGFR3)
- Cystic fibrosis (CFTR)
- Dentatorubral-pallidoluysian atrophy
- Duchenne/Becker muscular dystrophy (dystrophin)
- Ehlers-Danlos syndrome
- Fabry disease
- Factor V Leiden mutation (Factor V)

Genetic & Molecular Biologic Diagnostics

- Factor XIII deficiency, congenital (Factor XIII beta globulin)
- Familial adenomatous polyposis coli (APC)
- Familial Mediterranean fever (MEFV)
- Fanconi anemia (FACC, FACD)
- Fragile X syndrome, FRAXA (FMR-1)
- Friedreich's ataxia (FRDA frataxin)
- Gaucher disease (GBA acid beta glucosidase)
- Hemochromatosis (HFE)
- Hemoglobin E thalassemia
- Hemoglobin S and/or C

Genetic & Molecular Biologic Diagnostics

- Hemophilia A/VWF (Factor VIII)
- Hemophilia B (Factor IX)
- Hereditary amyloidosis (TTR variants)
- Hereditary deafness (GJB2 Connexin-26, 32)
- Hereditary neuropathy with pressure palsies (HNPP)
- Hereditary non-polyposis colorectal cancer (HNPCC) (MLH1, MSH2, MSH6. MSI)
- Hereditary pancreatitis (PRSS1)
- Hereditary polyposis coli (APC)
- Hereditary paraganglioma (SDHD, SDHB)

Genetic & Molecular Biologic Diagnostics

- Hereditary spastic paraplegia 3 (SPG3A) and 4 (SPG4, SPAST)
- Huntington's disease
- Hypochondroplasia (FGFR3)
- Jackson-Weiss syndrome (FGFR2)
- Kallmann syndrome (FGFR1)
- Kennedy disease (SBMA)
- Leber hereditary optic neuropathy (LHON)
- Leigh Syndrome and NARP (neurogenic muscle weakness, ataxia, and retinitis pigmentosa)
- Long QT syndrome

Genetic & Molecular Biologic Diagnostics

- Limb girdle muscular dystrophy (LGMD1, LGMD2)
- Marfan's syndrome
- Medium chain acyl coA dehydrogenase deficiency (ACADM)
- Medullary thyroid carcinoma
- MELAS (mitochondrial encephalomyopathy with lactic acidosis and stroke-like episodes) (MTTL1, tRNAleu)
- Mucopolysaccharidoses type 1 (MPS-1)
- Muenke syndrome (FGFR3)
- Multiple endocrine neoplasia type 1
- MYH-associated polyposis (MYH) (see below)
- Myoclonic epilepsy (MERRF) (MTTK tRNAlys)

Genetic & Molecular Biologic Diagnostics

- Myotonic dystrophy (DMPK, ZNF-9)
- Neimann-Pick disease (NPC1, NPC2 sphingomyelin phosphodiesterase)
- Nephrotic syndrome, congenital (NPHS1, NPHS2)
- Neurofibromatosis type 1 (neurofibromin)
- Neurofibromatosis type 2 (Merlin)
- Neutropenia, congenital cyclic
- Oculopharyngeal muscular dystrophy (OPMD) Pfeiffer syndrome (FGFR1)
- Prader-Willi-Angelman syndrome (SNRPN, GABRA5, NIPA1, UBE3A, ANCR GABRA)

Genetic & Molecular Biologic Diagnostics

- Primary dystonia (TOR1A DYT1)
- Prothrombin (Factor II, 20210G> A mutation)
- Pyruvate kinase deficiency (PKD)
- Retinoblastoma (Rh)
- Rett syndrome (MECP2)
- Saethre-Chotzen syndrome (TWIST, FGFR2)
- SHOX-related short stature
- Spinal muscular atrophy (SMN1, SMN2)
- Spinocerebellar ataxia (SCA types 1, 2, 3 (MJD), 6 (CACNA1A), 7, 8, 10, 17 and DRPLA)
- Tay-Sachs disease (HXA hexosaminidase A)

Genetic & Molecular Biologic Diagnostics

- Thanatophoric dysplasia (FGFR3)
- Von Hippel-Lindau syndrome (VHL)
- 22q11 deletion syndromes (DCGR CATCH-22)

Radiation Oncology/Therapy

- Destruction of tumors/lesions; sparing of normal surrounding tissues
- Crude techniques in ’80s & early ’90s:
  - radiosensitivity of tissues
- Performed by Radiation Oncologists
  - radiation therapy / radiation oncology
  - consultation with surgeons sometimes
- POS: Hospital / Freestanding / “Office”

Ionizing Radiation

electromagnetic / charged particle

DNA damage/cross-link/cell reproduction

- high-energy photons
- high-energy electrons
- protons / carbon ions / helium ions
- gamma ray
- linear accelerator (LINAC) / radioactive isotope

Unit of radiation: Gy (gray) - joule/kg

- 1 Gy = 100 cGy (centigray) = 100 rads (caveat: don't confuse with Tesla units)

External (Beam) Radiation Tx

EBRT = Teletherapy (CPT)

- 80%-90% of RT services performed
- 3D-CRT (3-dimensional conformal RT)
- IMRT (intensity-modulated RT)
- Proton Beam / Neutron Beam therapy
- Stereotactic Radiosurgery (SRS)
- Stereotactic Body Radiotherapy (SBRT)
- IGRT (image-guided RT) / tomotherapy
- 4D-CRT (4-dimensional conformal RT)

Internal Radiation Therapy

- Brachytherapy
  - radioisotopic seeds, implants, liquid
  - MammoSite
- Systemic RT
  - po / iv
  - Iodine-131 for thyroid cancer
- Radioembolization
  - yttrium Y-90 isotope microspheres for hepatocellular carcinoma

EBRT – 3D-CRT

- Standard, “conventional” RT
  - replaces conventional 2D simulation x-ray
- High precision CT (MRI) planning
- Radiation conforms to shape and target volume of tumor/lesion
- Sophisticated computerized treatment planning calculates 3D radiation dosage
- Precise delivery of radiation to target; minimize exposure to normal tissue
- Indication – solid tumors
- Duration – daily sessions x 2-7 weeks

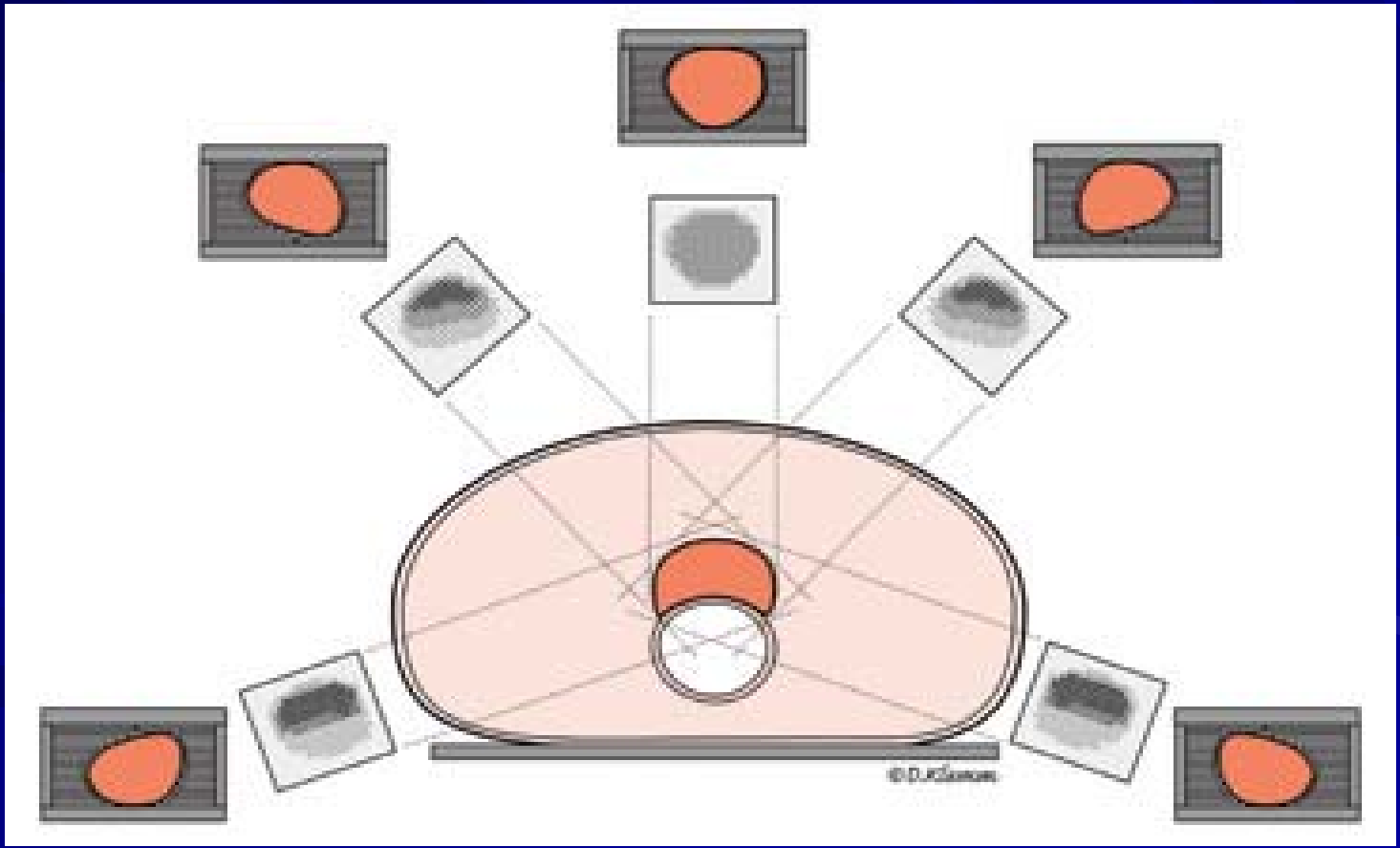
EBRT – 4D-RT

- 3D-CRT +
- Computer-assisted tracking of CT imaging of moving targets
- Indication – lung, breast, pancreas, liver tumors susceptible to respiratory or diaphragmatic movement

EBRT - IMRT

- Advanced form of 3D-CRT
- Sophisticated computer-assisted treatment planning of precise 3D radiation: target volume & “inverse planning”
- Varying (non-uniform) radiation intensities (beamlets) delivered through computer-controlled multileaf collimator
- Improved precision around tumor edges over 3D-CRT
- Indications – high radiation (e.g., >75 Gy); proximity to critical organs; unusual, irregular anatomical shapes (convex, concave). Prostate; H&N tumors
- Duration – daily sessions x 2-7 weeks

EBRT - IMRT



EBRT – IMRT vs 3D-CRT

- No comparative RCT of IMRT vs 3D-CRT
- Observational studies suggest that IMRT offers less radiation toxicity at equivalent radiation dosimetry
- IMRT + brachytherapy for prostate ca
  - low-moderate IMRT dosimetry (35-45 Gy)
  - no data on improved outcome over 3D-CRT
  - ? observational data on toxicity
- Cost-effectiveness

EBRT - IGRT

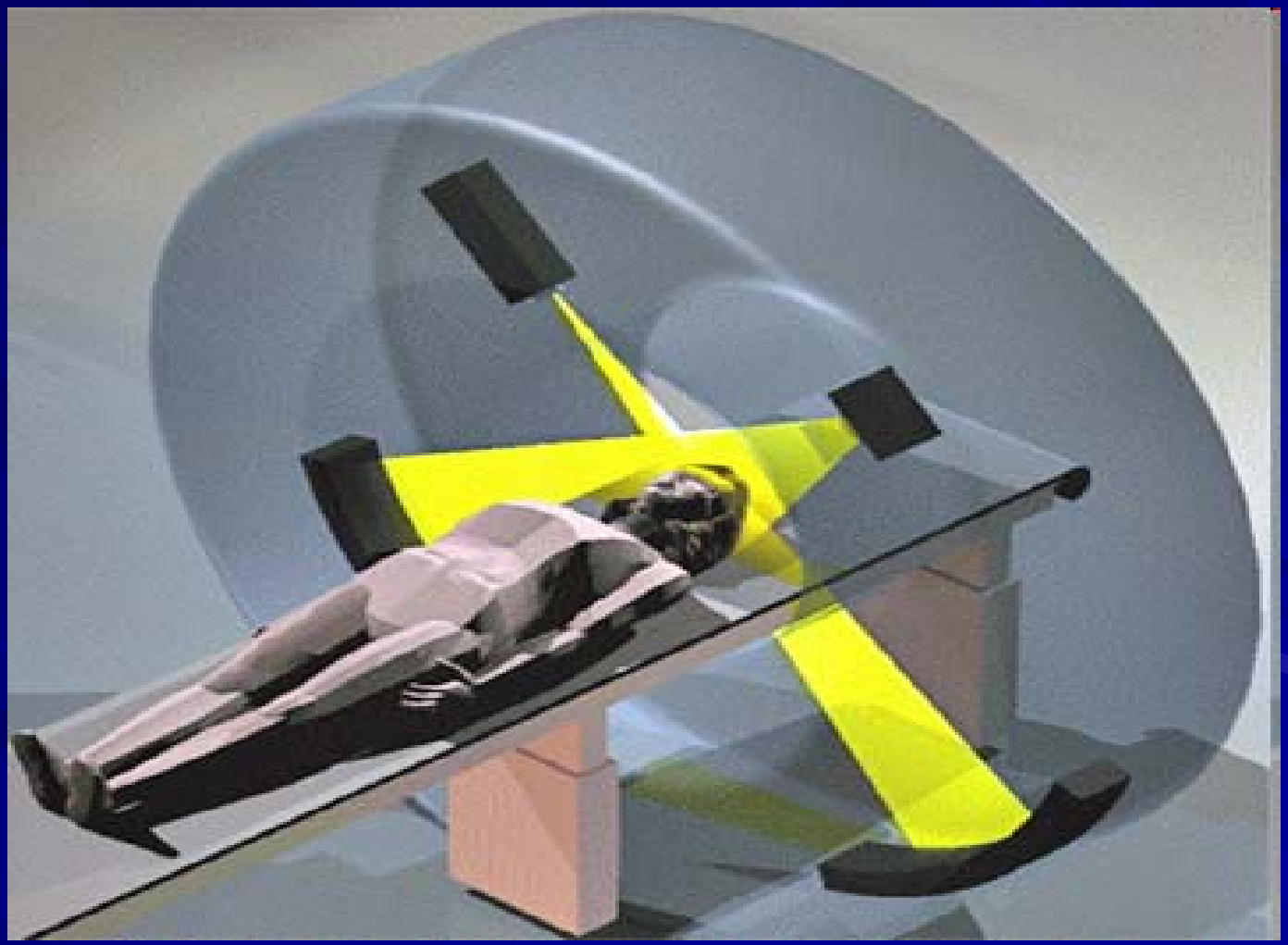
- CT/MRI imaging directly incorporated into radiation delivery machines (Trilogy / Tomotherapy)
- Daily confirmation of tumor and patient positioning – used in various RT techniques – most commonly in IMRT for prostate cancer
- Controversy – reduces target volume (?) but no study to demonstrate improved prostate cancer outcome or less morbidity

EBRT - IGRT

EBRT - Tomotherapy

- IMRT delivery with a twist
- Slice/sectional therapy
- Form of IGRT – real-time imaging with CT incorporated into LINAC
- Radiation delivery via narrow arc (slice) rotation around patient
- Think of it as a special form of MLC

EBRT - Tomotherapy



EBRT - Tomotherapy

Internal Radiation Therapy

- Brachytherapy
  - radioisotopic seeds, rods, liquid
  - interstitial implant or intracavitary device
  - permanent or temporary implants
  - boost or stand-alone therapy
  - “HDR” brachytherapy

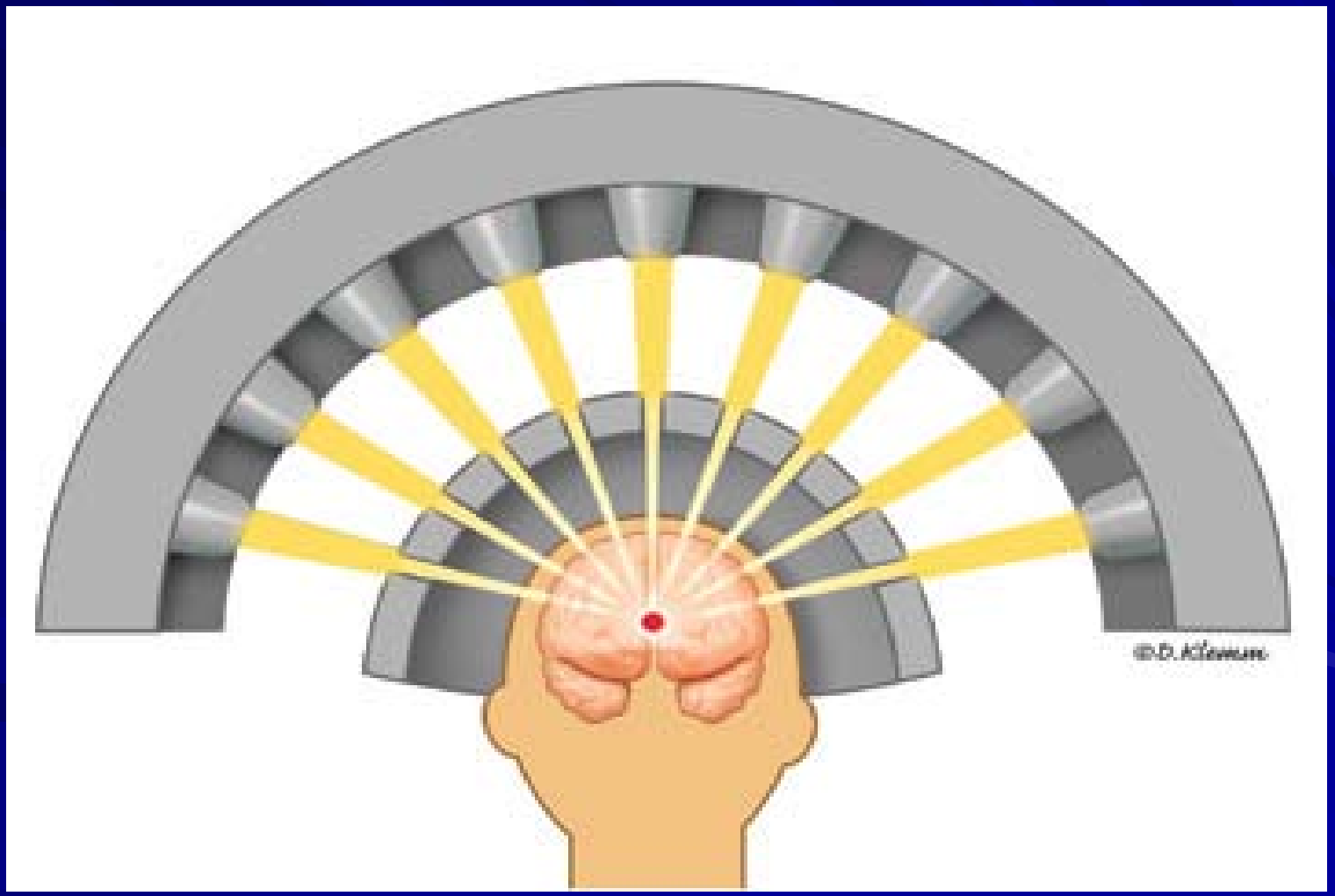
Brachytherapy

- Permanent I-125 radiation seed implants for prostate cancer
  - Duration: permanent; radiation dissipates
- Temporary brachytherapy delivered via intracavitary catheters (rods) for cervical cancer
  - Duration: several weeks
- Liquid isotopes in balloon catheters for breast cancer (MammoSite)
  - Duration: 5 days

Stereotactic Radiosurgery (SRS)

- Multiple radiation beam convergence on target tumor (brain)
- High radiation dose to tumor
- Minimal radiation to surrounding tissues
- Gamma Knife (may also be Cyberknife)
  - head frame for immobilization
- Indications: intracranial tumors/mets, AVM, acoustic neuroma
- Duration – 1 session

EBRT – GammaKnife



Stereotactic Body Radiotherapy (SBRT)

- High dose radiation
- Cyberknife - robotic arm with LINAC
- Multiple positions
- Indications: Spinal tumors/mets, stage 1a/1b NSCLC
- Fractionation – up to 5 fractions (sessions)

Cyberknife

Charged Particle: Proton Beam

- Particle accelerator targets beam of high energy protons toward target tumor
- Dissipation of energy (decelerate and energy transfer) into tissue, resulting in ionizing radiation
- Bragg peak – energy peaks near end of finite range of proton beam, then drops off to near zero
- Indications: uveal tract tumor, chordoma, and (prostate cancer)
- Widespread use limited by high cost and IMRT

IMRT - IGRT Billing

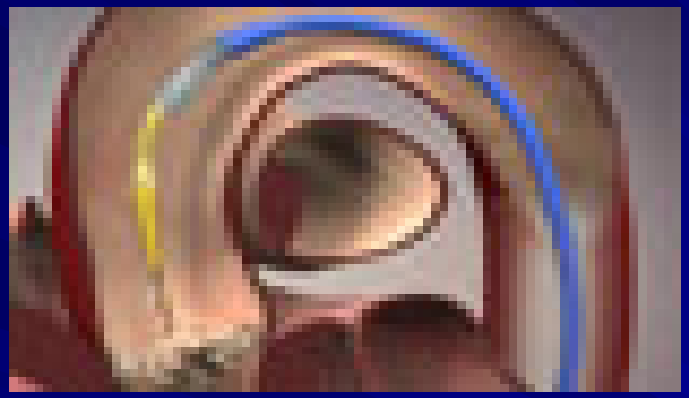
- IMRT – Intensity Modulated Radiation Therapy
- IGRT – Image Guided Radiation Therapy
- 77418 – Intensity modulated treatment delivery, single or multiple fields/arcs, binary, dynamic MLC, per treatment session
  - $740 x 40 ~= $30,000
- 77421 – Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy
  - CMS-Medicare: Packaged/Bundled service under OPPS and ASC
  - $150 x 40 = $6,000
  - ASC status indicator N1 / OPSI status N
- Calypso intrafraction image tracking device - IGRT in IMRT
  - 0197T - Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy
  - A4648 - Tissue marker, implantable, any type, each

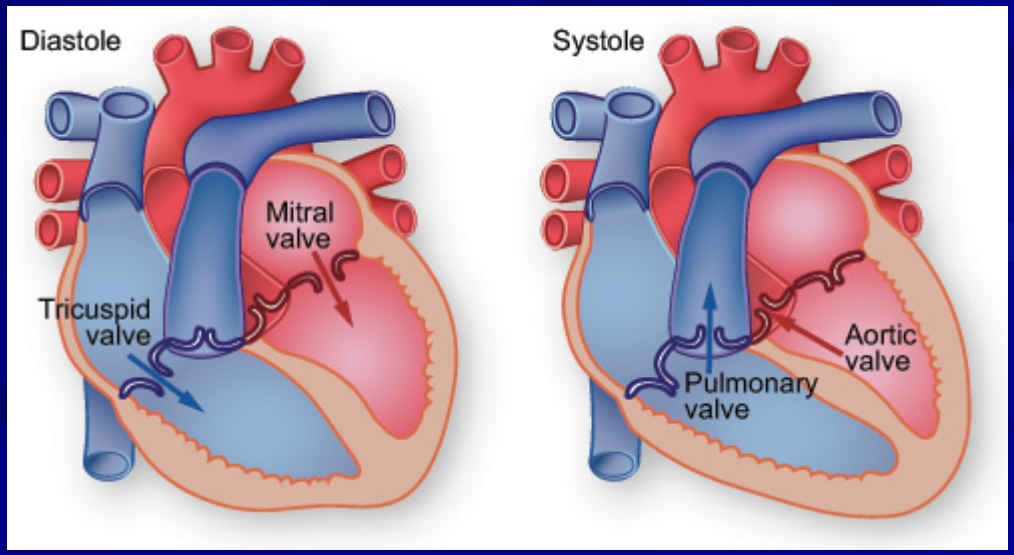
E-S Transcatheter Aortic Valve

Transcatheter Aortic Valve Implant (TAVI)

- Nov. 2011 – FDA approval of ***Edwards-Sapien* TAV**
- Estimated cost: $30K device / $75K total
- PARTNER clinical trials – published 2010
  - Non-inferior to surgical (open) AVR: 1-year mortality 25%
  - TAVI neurologic events higher 30 days (5.5% vs 2.4%) and 1 year (8.3% vs 4.3%)
  - Major vascular events higher 30 days (11% vs 3.2%)
- Reserved for patients medically too high-risk for surgical AVR / medically inoperable.
- 32% AV patients high-risk for open AVR surgery – thoracotomy / CPB
- ***CoreValve*** (by Medtronic) - IDE status from FDA Oct. 2010
  - Thinner device / already in use in Europe / US pivotal trial Dec. 2010

E-S Transcatheter Aortic Valve





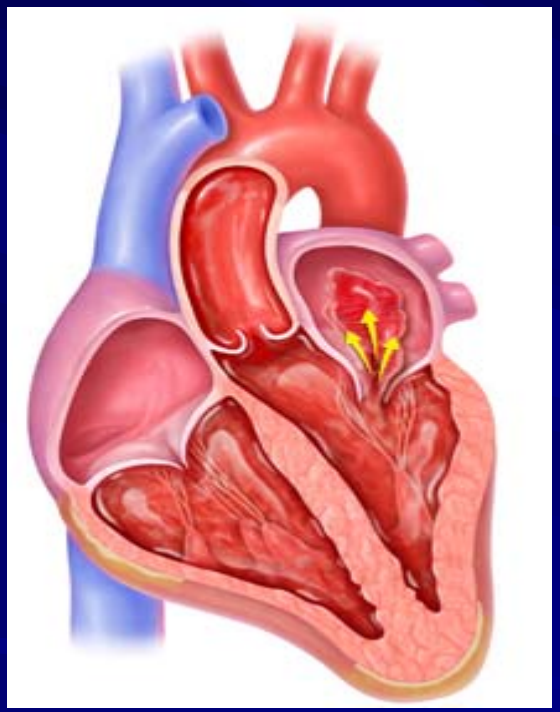
Transcatheter Aortic Valve Implant (TAVI)

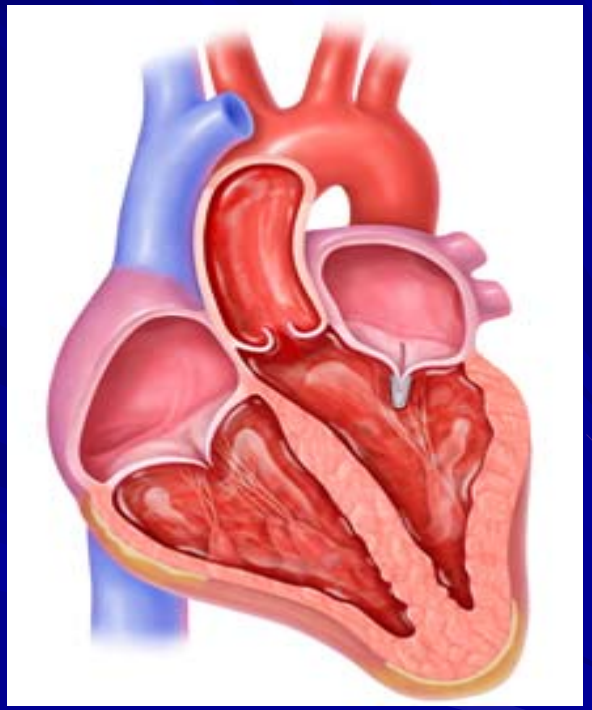
- 0256T - Implantation of catheter-delivered prosthetic aortic heart valve; endovascular approach
- 0257T - Implantation of catheter-delivered prosthetic aortic heart valve; open thoracic approach (eg, transapical, transventricular)
  - Includes temporary cardiac pacing, contrast injection, and image guidance / fluoroscopic radiological supervision and interpretation.
  - Excludes minithoracotomy (32095 - Thoracotomy, limited, for biopsy of lung or pleura / 33243 - Removal of pacing cardioverter-defibrillator electrode(s); by thoracotomy)
  - Excludes cardiac catheterization (934xx) at time of TAVI!
- 35.22 – Other replacement of aortic valve

Transcatheter Mitral Valve Implant (TMVI – MitraClip)

- Transcatheter percutaneous mitral valve repair via MitraClip device (Abbott / Evalve)
- PMA submitted to FDA in 2010
  - FDA review in 2011
- Abbott worldwide recall May 2010
- EVEREST II clinical trials – published April 2011
  - MitraClip less effective than surgical (open) MVR
  - 23% with Grade 3+/4+ residual MR vs surgery at d/c
  - At 1-year, 20% MitraClip patients required MVR surgery
- 93799 - Unlisted cardiovascular service or procedure
- 92987 - Percutaneous mitral valve balloon valvuloplasty
- 35.24 – Other replacement of mitral valve

MitraClip

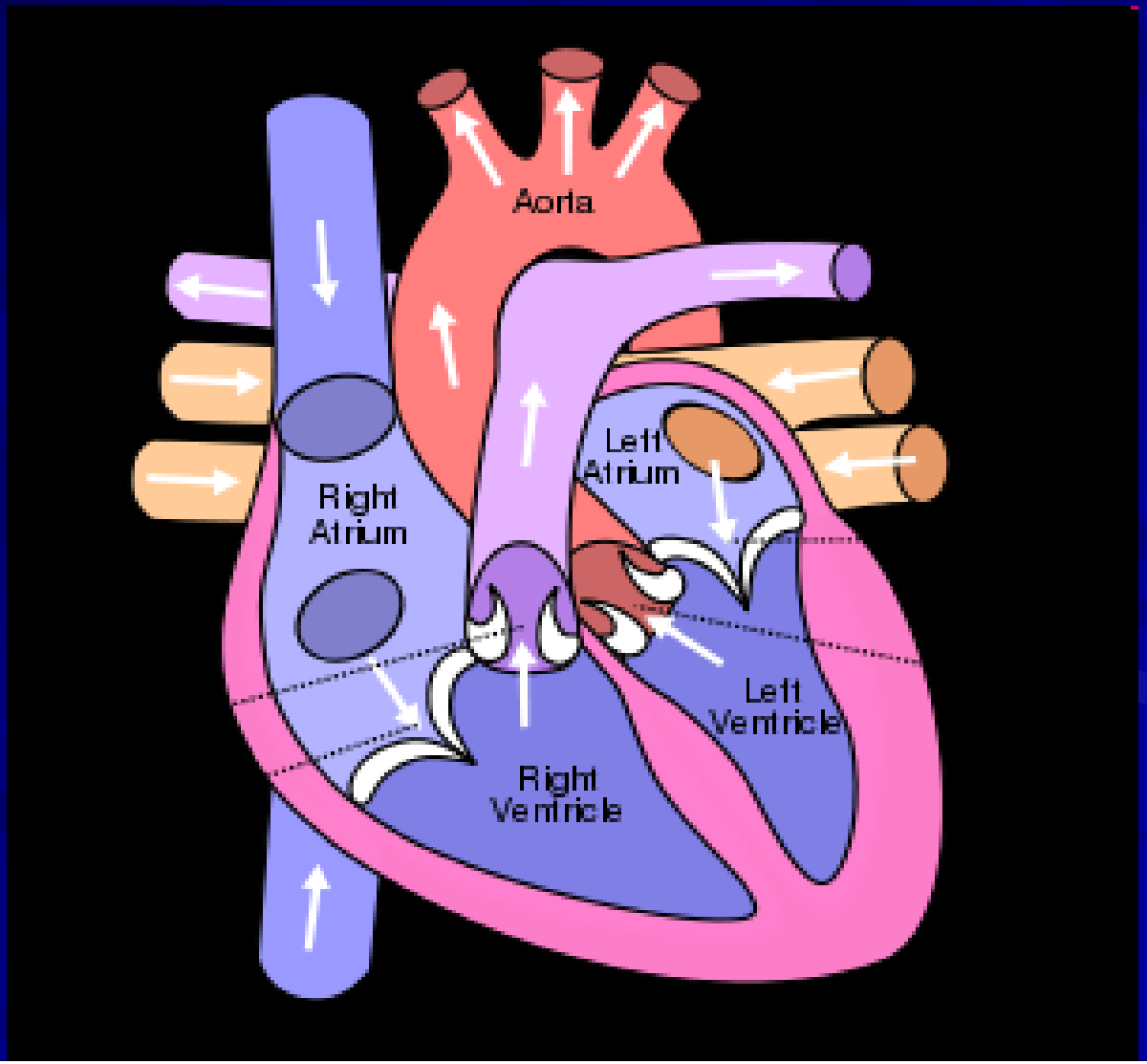




Transcatheter Pulmonary Valve Implant (TPVI – Melody)

- FDA Humanitarian Device Exemption (HDE) approval on January 25, 2010
  - Prior h/o congenital heart repair, with RVOT dysfunction.
  - High risk for repeat surgery or multiple prior thoracotomies
- 0262T: Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach
- US Melody TPV trial - prospective multicenter uncontrolled trial from five clinical sites

Transcatheter Pulmonary Valve Implant (TPVI – Melody)



Transcatheter Pulmonary Valve Implant (TPVI – Melody)

- 0262T - Implantation of catheter-delivered prosthetic pulmonary valve, endovascular
- 35.26 - Other replacement of pulmonary valve
- 02RH3JZ / 02RH4JZ - Surgery, heart and great vessels, replacement, pulmonary valve, synthetic substitute, percutaneous or percutaneous endoscopic

CPT Valvular Surgery Codes

33400	Valvuloplasty, aortic valve; open, with cardiopulmonary bypass	60.59	$2,222
33401	Valvuloplasty, aortic valve; open, with inflow occlusion	41.06	$1,481
33403	Valvuloplasty, aortic valve; using transventricular dilation, with cardiopulmonary bypass	41.24	$1,487
33405	Replacement, aortic valve, with cardiopulmonary bypass; with prosthetic valve other than homograft or stentless valve	63.27	$2,282
33410	Replacement, aortic valve, with cardiopulmonary bypass; with stentless tissue valve	68.51	$2,471
33411	Replacement, aortic valve; with aortic annulus enlargement, noncoronary cusp	89.23	$3,218
33412	Replacement, aortic valve; with transventricular aortic annulus enlargement (Konno procedure)	68.51	$2,470
33420	Valvotomy, mitral valve; closed heart	36.89	$1,330
33422	Valvotomy, mitral valve; open heart, with cardiopulmonary bypass	46.23	$1,667
33425	Valvuloplasty, mitral valve, with cardiopulmonary bypass	71.32	$2,572
33426	Valvuloplasty, mitral valve, with cardiopulmonary bypass; with prosthetic ring	65.19	$2,351
33427	Valvuloplasty, mitral valve, with cardiopulmonary bypass; radical reconstruction, with or without ring	68.31	$2,463
33430	Replacement, mitral valve, with cardiopulmonary bypass	75.16	$2,711
33999	Unlisted procedure, cardiac surgery		

ICD-9 Valvular Surgery Codes

- 35.2 Replacement of heart valve
  - 35.20 Replacement of unspecified heart valve
  - 35.21 Replacement of aortic valve with tissue graft
  - 35.22 Other replacement of aortic valve
  - 35.23 Replacement of mitral valve with tissue graft
  - 35.24 Other replacement of mitral valve
  - 35.25 Replacement of pulmonary valve with tissue graft
  - 35.26 Other replacement of pulmonary valve
  - 35.27 Replacement of tricuspid valve with tissue graft
  - 35.28 Other replacement of tricuspid valve
- 35.9 Other operations on valves and septa of heart
  - 35.91 Interatrial transposition of venous return
  - 35.95 Revision of corrective procedure on heart
  - 35.96 Percutaneous valvuloplasty
  - 35.99 Other operations on valves of heart
- 35.1 Open heart valvuloplasty without replacement

Cardiac Contractility Modulation (CCM)

- On radar screen in hospital contracting/special carve-out in 2009.
- Optimizer III CCM system – Impulse Dynamics
- Delivers non-excitatory impulses to the heart during the absolute refractory period to enhance the strength of the heart, for treatment of CHF (congestive heart failure).
- "The ability of CCM signals to enhance heart strength is currently under investigation."

CCM System – Optimizer III

Codes for CCM System

17.51 Implantation of rechargeable cardiac contractility modulation [CCM], total system

17.52 Implantation or replacement of cardiac contractility modulation [CCM] rechargeable pulse generator only

33202-33249 Pacemakers/Implantable Defibrillators

Lumbar Spinal Stenosis - M I L D

- Minimally Invasive Lumbar Decompression
  - new treatment for lumbar spinal stenosis
  - different procedure than percutaneous discectomy, laser discectomy, or microdiscetomy
  - outpatient procedure performed under local anesthesia, IV moderate sedation, or MAC
  - image-guided percutaneous access of inter-laminar space, with mild re-construction (removal of tissue and bone to decompress the spine)

Lumbar Spinal Stenosis - M I L D

Lumbar Spinal Stenosis - M I L D

- Covered by Medicare?
- 900,000 patients annually; 220,000 surgeries
- “Vertos Medical, Inc. is . . . currently enrolling the first phase of what we anticipate to be a four-phased clinical trial. Phase I is expected to enroll 75 patients at up to 30 study centers. Adult patients with symptomatic LSS who meet the study enrollment criteria will be offered the *mild*® procedure as an alternative to surgery or continued standard non-surgical medical management.”

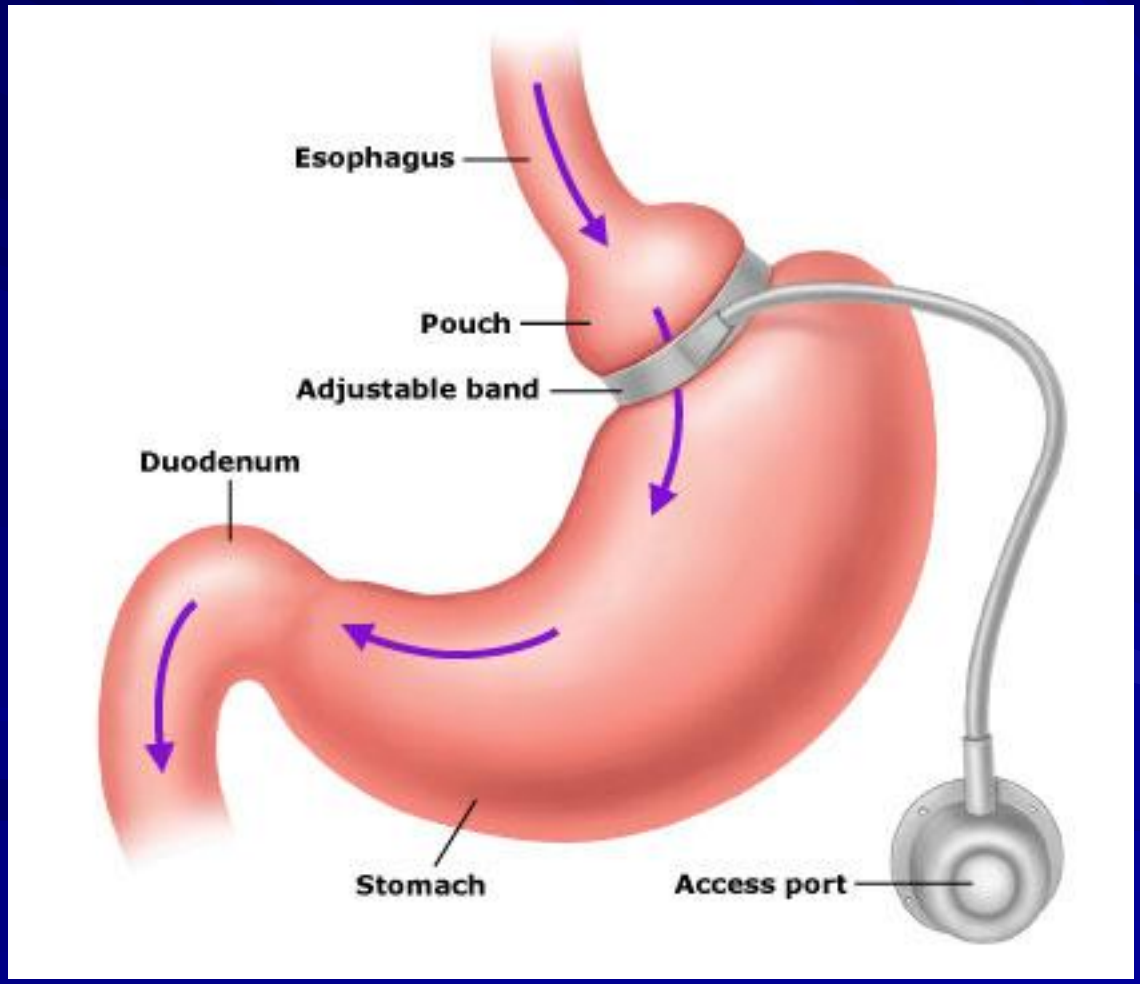
CPT codes for M I L D

- **64999** Unlisted Procedure of the Nervous System
- **63030** Laminotomy (hemi-laminectomy); open and endoscopic; lumbar
- **62287** Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method, single or multiple levels, lumbar (eg, manual or automated percutaneous discectomy, percutaneous laser discectomy)
- **77002** Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)
- **77012** Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation

Bariatric Surgery - Gastric Laparoscopic Banding

- Gastric restrictive procedure for weight loss in severe obesity, BMI $\geq$35
- Placement of adjustable silicone band at entrance to stomach, delaying food passage and causes satiety
- Less invasive than open or laparoscopic gastric bypass surgery (e.g., Roux-en-Y procedure)

Gastric Lap Band



Gastric Lap Band

- Covered by Medicare and commercial payers, along with open or laparoscopic Roux-en-Y gastric bypass (43846, 43847, 43644, 43645) and duodenal switch (43845) surgeries, etc.
- 43770 Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
- 43771 Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
- 43772 Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
- 43773 Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
- 43774 Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
- Major surgeries – 90-day global surgery (payment) period

Gastric Lap Band

- S2083 Gastric band adjustment via injection or aspiration of saline through subcutanous port
  - simple, 10-min office-based procedure
  - providers bill as much as $2000 per adjustment
  - fluoroscopic guidance rarely necessary
- Typical schedule of post-op adjustments:
  - 3 in first 3 months (surgery global); 2-3 thereafter in first year
  - 1-2 adjustments in post-op year two
  - 1-2 adjustments in post-op year three (rarely)
- Establish Payment Policy
  - Payable number and interval. Don't forget Global Surgical.
  - Office-based only (should not be ASC or hospital OP)
  - Bundled services (e.g., E/M) vs. separately allowable – adjust fee schedule accordingly.

Viscosupplementation
(Image Guidance)

- Pharmacologic therapy of osteoarthritis
- Intraarticular injection of hyaluronans
  - Hyalgan®, Supartz®, Nuflexxa®, Synvisc®, Orthovisc®
  - Glycosaminoglycan found in epithelial, connective, and neural tissues
  - Injected into knee joints for osteoarthritic pain, sometimes in conjunction with steroids

Viscosupplementation
(Image Guidance)

- Ultra Sound guidance for knee joint injection
  - Generally not medically necessary and not standard of practice
  - 76942 Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization)
  - J7321, J7322, J7323, J7324 and J3490

- Obstetrics Ultrasound (unrelated topic)
  - 768XX code series (e.g., 76801, 76810, 76828)
  - Not including 590XX code series

Facet Joint Injection
(Image Guidance)

- Facet Joint (spinal) injection
  - Also referred to as medial branch blocks (MBB) to anesthetize the innervation of the cervical (neck) or lumbar (low back) zygapophyseal (facet) joint, for chronic pain that is caused by facet joint
  - Questionable efficacy; clinical trials lacking
  - Fluoroscopic (x-ray imaging) guidance for needle placement is standard of practice
  - CT guidance NOT the standard of practice and not cost-effective

Facet Joint Injection
(Image Guidance)

77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, transforaminal epidural, subarachnoid, paravertebral facet joint, paravertebral facet joint nerve, or sacroiliac joint), including neurolytic agent destruction
77002	Fluoroscopic guidance for needle placement (eg, biopsy, aspiration, injection, localization device)
64622	Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, single level
64623	Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, each additional level (List separately in addition to code for primary procedure)
64626	Destruction by neurolytic agent, paravertebral facet joint nerve; cervical or thoracic, single level
64627	Destruction by neurolytic agent, paravertebral facet joint nerve; cervical or thoracic, each additional level (List separately in addition to code for primary procedure)

Platelet-Rich Plasma

- Platelets contain platelet-derived growth factors
- Autologous platelet-rich plasma reinjected into tissue or joint space for bone growth, tendonopathy or ligament repair, in conjunction with orthopedic surgery
- Considered investigational/experimental
- 38206, 38230, 86999, 20926 S9055, P9020

CPT / HCPCs codes - PRP

38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38230	Bone marrow harvesting for transplantation
20926	Tissue grafts, other (eg, paratenon, fat, dermis)
S9055	Procuren or other growth factor preparation to promote wound healing
P9020	Platelet rich plasma, each unit
86999	Unlisted transfusion medicine procedure

Genomics/Genetic Testing

- Genomics: The study of (human) genome
- Genome: The full complement of genetic information encoded on a complete set of chromosomes
- Human Genome Project mapped out entire human genome in 2003
  - 3 trillion base pairs
  - Single nucleotide polymorphisms (SNPs) occur per 1000 base pairs and identify genes of health traits
  - Proliferation of genetic testing and *Personalized Medicine*

Genomics: Personalized Medicine

"The application of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, and help determine a person's predisposition to a particular disease or condition."

U.S. Congress

- New age of ***Theragnostics***

Personalized Medicine
("Theragnostics")

- Genetic Expression in Tumor Tissue for Breast Cancer Prognosis
  - Analysis of gene expression markers to predict recurrence of breast cancer after surgery, radiation therapy, and hormonal therapy
  - Small tumor, negative lymph nodes, hormone receptor (estrogen; HER-2) positivity = good prognosis
    - 85% disease-free with Tamoxifen alone; avoiding toxicities of chemotherapy
    - Commercially available assay (testing): Oncotype Dx / MammaPrint / Mammostrat / Breast Cancer Gene Expression Ratio

Personalized Medicine
("Theragnostics")

- Genetic Testing for Warfarin Dose
  - Warfarin (Coumadin) drug therapy – anticoagulation of blood – to prevent/treat thromboembolic events
  - Initial and steady-state dosing of warfarin varies among individual patients
  - Narrow therapeutic window
  - CYP2C9 and VKORC1 genetic testing to predict fast vs. slow metabolizers
  - FDA includes warfarin sensitivity testing in drug labeling, of CYP2C9 and VKORC1 genotypic variants.

Personalized Medicine
("Theragnostics")

- Co-receptor tropism testing in HIV drug treatment regimen
- 3 initial classes of HIV anti-viral drugs
  - NRTIs (nucleotide reverse transcriptase inhibitor)
  - NNRTIS
  - PI (protease inhibitors)
- New classes
  - Integrase inhibitors
  - CCR5 antagonists
  - Fusion inhibitors
- Trofile (Monogram Bioscience) and SensiTrop (Pathway-Quest Diagnostics) tropism testing for CCR5 antagonists

Genomic/Genetic Testing - Codes

- **S3841** Genetic testing for retinoblastoma
- **S3845** Genetic testing for alpha-thalassemia
- **S3847** Genetic testing for Tay-Sachs disease
- **S3848** Genetic testing for Gaucher disease
- **S3849** Genetic testing for Niemann-Pick disease
- **S3850** Genetic testing for sickle cell anemia
- **S3851** Genetic testing for Canavan disease
- **S3800** Genetic testing for amyotrophic lateral sclerosis (ALS)
- **S3853** Genetic testing for myotonic muscular dystrophy
- **S3842** Genetic testing for Von Hippel-Lindau disease
- **S3846** Genetic testing for hemoglobin E beta-thalassemia
- **S3861** Genetic testing, sodium channel, voltage-gated, type V, alpha subunit (SCN5A) and variants for suspected Brugada Syndrome
- **S3831** Single-mutation analysis (in individual with a known MLH1 and MLH2 mutation in the family) for hereditary nonpolyposis colorectal cancer (HNPCC) genetic testing
- **S3835** Complete gene sequence analysis for cystic fibrosis genetic testing
- **S3855** Genetic testing for detection of mutations in the presenilin - 1 gene
- **S3860** Genetic testing, comprehensive cardiac ion channel analysis, for variants in 5 major cardiac ion channel genes for individuals with high index of suspicion for familial long QT syndrome (LQTS) or related syndromes
- **S3862** Genetic testing, family-specific ion channel analysis, for blood-relatives of individuals (index case) who have previously tested positive for a genetic variant of a cardiac ion channel syndrome using either one of the above test configurations or confirm
- **S3830** Complete MLH1 and MLH2 gene sequence analysis for hereditary nonpolyposis colorectal cancer (HNPCC) genetic testing
- **S3837** Complete gene sequence analysis for hemochromatosis genetic testing
- **S0265** Genetic counseling, under physician supervision, each 15 minutes
- **S3866** Genetic analysis for a specific gene mutation for hypertrophic cardiomyopathy (HCM) in an individual with a known HCM mutation in the family
- **S3870** Comparative genomic hybrization (CGH) microarray testing for developmental delay, autism spectrum disorder and/or mental retardation
- **S3713** Kras mutation analysis testing

Genomic/Genetic Testing - Codes

- CPT codes for array-based evaluation of multiple molecular markers:
- 88384: Array-based evaluation of multiple molecular probes: 11 through 50 probes
- 88385: 51 through 250 probes
- 88386: 251 through 500 probes
- When less than 11 probes are prepared and evaluated, the services are coded using CPT codes 83890-83914 as appropriate.
- CPT genetic testing modifier specific to CYP2 genes:
  - -9B: CYP2 genes, commonly called cytochrome p 450 (drug metabolism)
- CPT genetic testing modifier non-specific for VKORC1:
  - -9L metabolic-pharmacogenetics, not otherwise specified, may be used with the codes.

Genomic/Genetic Testing - Codes

- **83908** Molecular diagnostics; amplification, signal, each nucleic acid sequence
  - **83898** Molecular diagnostics; amplification, target, each nucleic acid sequence
  - **83900** Molecular diagnostics; amplification, target, multiplex, first 2 nucleic acid sequences
  - **83901** Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond 2 (List separately in addition to code for primary procedure)
  - **83890** Molecular diagnostics; molecular isolation or extraction, each nucleic acid type (ie, DNA or RNA)
  - **83907** Molecular diagnostics; lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue), each specimen
  - **83896** Molecular diagnostics; nucleic acid probe, each
  - **83892** Molecular diagnostics; enzymatic digestion, each enzyme treatment
  - **83902** Molecular diagnostics; reverse transcription
  - **83909** Molecular diagnostics; separation and identification by high resolution technique (eg, capillary electrophoresis), each nucleic acid preparation
  - **83891** Molecular diagnostics; isolation or extraction of highly purified nucleic acid, each nucleic acid type (ie, DNA or RNA)
  - **83893** Molecular diagnostics; dot/slot blot production, each nucleic acid preparation
  - **83894** Molecular diagnostics; separation by gel electrophoresis (eg, agarose, polyacrylamide), each nucleic acid preparation
  - **83897** Molecular diagnostics; nucleic acid transfer (eg, Southern, Northern), each nucleic acid preparation
  - **83903** Molecular diagnostics; mutation scanning, by physical properties (eg, single strand conformational polymorphisms [SSCP], heteroduplex, denaturing gradient gel electrophoresis [DGGE], RNA'ase A), single segment, each
  - **83904** Molecular diagnostics; mutation identification by sequencing, single segment, each segment
  - **83905** Molecular diagnostics; mutation identification by allele specific transcription, single segment, each segment
  - **83906** Molecular diagnostics; mutation identification by allele specific translation, single segment, each segment
  - **83912** Molecular diagnostics; interpretation and report
  - **83913** Molecular diagnostics; RNA stabilization

Genomic/Genetic Testing - Codes

87903	INFECT AGT GENOTYPE ANALYSIS BY NUCLEIC ACID,W/DRUG RESISTANCE
87901	INFECT AGT GENOTYPE ANALYSIS BY NUCLEIC ACID, HIV 1, REVERSE
87904	EACH ADD'L DRUG, UP TO 5 DRUGS
87900	INFECTIOUS AGENT DRUG SUSCEPTIBILITY PHENOTYPE PREDICTION USIN
87999	UNLISTED MICROBIOLOGY TEST
84999	UNLISTED CHEM/TOX TEST
87902	INFECTIOUS AGENT GENOTYPE ANALYSIS; HEPATITIS C VIRUS

Personalized Medicine
("Theragnostics")

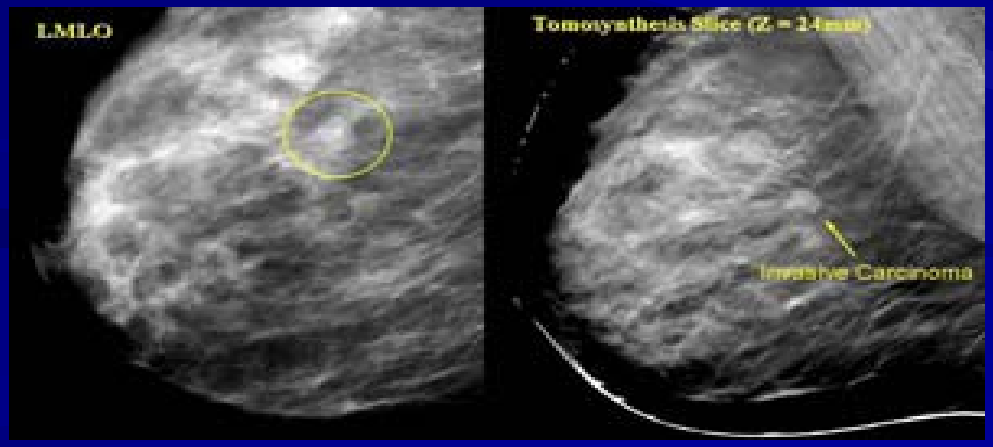
- Trofile
- OncoType Dx
- OncoVue
- Tamoxifen Gene Testing
- Warfarin receptor
- The Cancer Center is drawing increased media attention for its leading role in the development of targeted therapies and its move toward broad testing for genetic mutations in malignant tumors. Breast cancer researcher and oncologist **Leif Ellisen, MD, PhD**, and thoracic oncologist **Alice Shaw, MD, PhD**, spoke to *ABC News/World News with Charles Gibson* in June about the Cancer Center's progress in identifying the genetic mutations that underlie certain cancers. "This will allow us to match the tumor to effective drugs," said Ellisen.
- Treatment focused on particular tumor mutations—instead of the tumor's location in the body—"is the direction cancer care is going," noted Cancer Center oncologist **Lecia Sequist, MD, MPH**. *The Wall Street Journal* quoted Sequist in its report on improved outcomes with the drug Iressa (gefitinib) among particular types of lung cancer. At the American Society of Clinical Oncologists conference last spring, Sequist and other Cancer Center researchers announced that they have discovered that those patients whose cancer slows in response to the drug have a particular mutation in the EGFR gene.
- The *NCI Bulletin* also interviewed Sequist and Ellisen for its June cover story, "Making Personalized Cancer Treatment Routine." The Bulletin noted that under the leadership of pathologist **A. John Iafrate, MD, PhD**, director of the Mass General Molecular Pathology Laboratory, the Cancer Center routinely screens lung tumors for genetic mutations, profiling 13 genes, including EGFR, that are altered in a variety of cancers.
- (Dr. Leif Ellison, Mass General Hosp. Cancer Center:) "Every tumor has a genetic flaw, which is driving that cancer. And if we can figure out, for each individual tumor, what that flaw is, that will allow us to match the tumor to effective drugs."

Robot-Assisted Surgery

- Robot-assisted laparoscopic radical prostatectomy
- Robot-assisted endoscopic valve repair
  - (minimally invasive valve surgery)
- Robot-assisted coronary surgery
- S2900 - Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)
- 17.4 – robotic assisted procedure

Breast Tomosynthesis
(Hologic, GE, Siemens)

- Next-generation breast cancer screening beyond current digital mammography.
- Potential for improved sensitivity with lower FP rate.
- Currently awaiting FDA approval
- No CPT / HCPCS code



Breast Tomosynthesis

- Breast imaging - screening
  - Film screen (traditional) mammography
  - Digital mammography
  - (Breast ultrasound) – not recommended for screening
  - Breast MRI – not recommended for screening (or not recommended for average-risk screening) due to lower specificity.
  - Breast tomosynthesis?
    - Higher sensitivity and specificity? (small clinical trial)

Breast Tomosynthesis

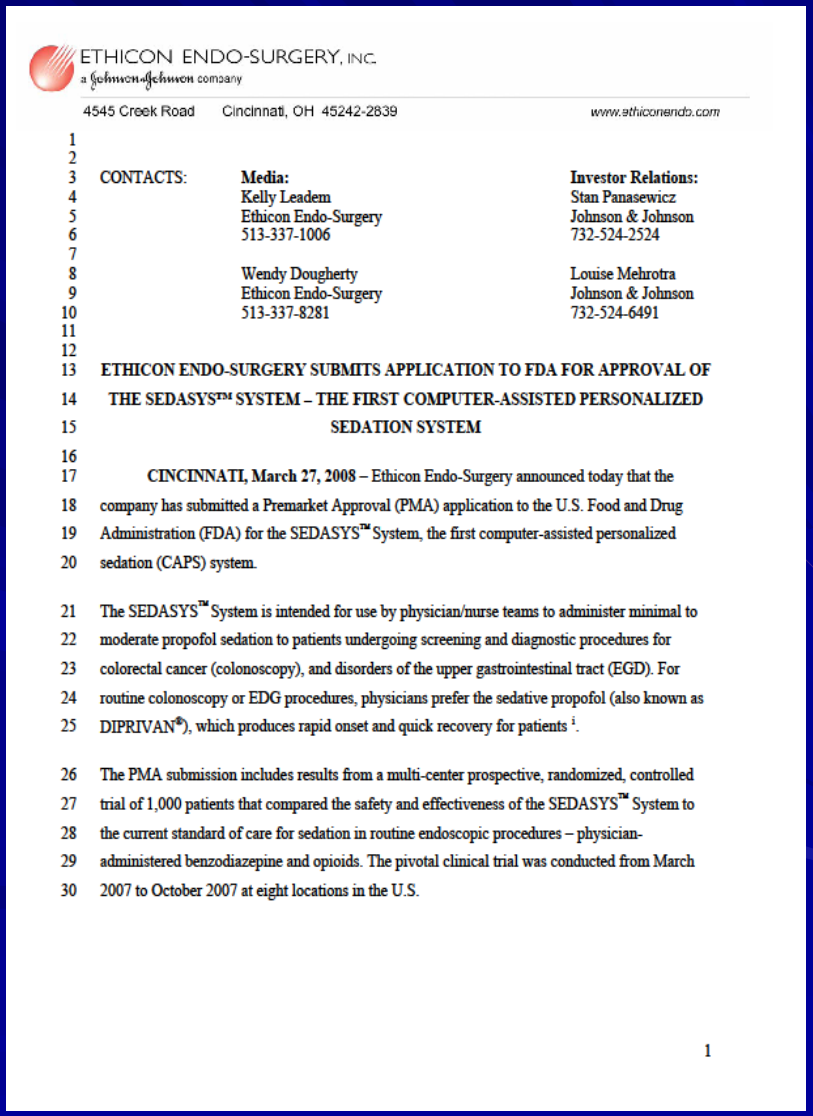
- Non-invasive, digital technology.
- 3D – multiple planes, loop image reconstruction.
- Reduced radiation and breast compression
- Early adoption = similar fate as FFDM (full-field digital mammography)?
- Expect similar “superiority” in screening for subgroups of women as FFDM.
- Projected cost increment: 17-20% > FFDM
  - $480K - $625K?

Breast Tomosynthesis - Update

- Received FDA approval in January 2011
- No specific CPT or HCPCS –
  - 76499 + G0202, G0204, or G0206 for FFDM
  - Incorrect to code 3-D reconstruction code + FFDM code
- Considered investigational by major payers (Blues; UHC; Aetna; CIGNA)
- No NCD or LCD

SEDASYS™ System
(J&J Ethicon Endo-Surgery)

- 8-center clinical trial in 2007.
- Currently awaiting FDA-approval. PMA submitted 03/2008.
- First ever Computer-Assisted Personalized Sedation system (CAPS) designed to deliver propofol sedation/anesthesia.
- Sizable ($5 B?) GI endoscopy anesthesia market.
- Anesthesia turf battle? Medical Necessity? Reimbursement?
- No CPT / HCPCS code



ETHICON ENDO-SURGERY, INC.
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ETHICON ENDO-SURGERY SUBMITS APPLICATION TO FDA FOR APPROVAL OF THE SEDASYS™ SYSTEM – THE FIRST COMPUTER-ASSISTED PERSONALIZED SEDATION SYSTEM

CINCINNATI, March 27, 2008 – Ethicon Endo-Surgery announced today that the company has submitted a Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA) for the SEDASYS™ System, the first computer-assisted personalized sedation (CAPS) system.

The SEDASYS™ System is intended for use by physician/nurse teams to administer minimal to moderate propofol sedation to patients undergoing screening and diagnostic procedures for colorectal cancer (colonoscopy), and disorders of the upper gastrointestinal tract (EGD). For routine colonoscopy or EDG procedures, physicians prefer the sedative propofol (also known as DIPRIVAN®), which produces rapid onset and quick recovery for patients [i].

The PMA submission includes results from a multi-center prospective, randomized, controlled trial of 1,000 patients that compared the safety and effectiveness of the SEDASYS™ System to the current standard of care for sedation in routine endoscopic procedures – physician-administered benzodiazepine and opioids. The pivotal clinical trial was conducted from March 2007 to October 2007 at eight locations in the U.S.

1

SEDASYS™ for Propofol Anesthesia (Monitored Anethesia Care)

- GI endoscopy (EGD, Colonoscopy, ERCP) can generally be effectively and safely performed by using intravenous (IV) moderate (conscious) sedation.
- Moderate (conscious) sedation drugs: Fentanyl Citrate, Midazolam (Versed), Demerol, Morphine, etc.
- Propofol – IV deep sedation anesthetic drug introduced to GI endoscopy anesthesia.

SEDASYS™ for Propofol Anesthesia

- Propofol anesthesia typically delivered by CRNA or anesthesiologist.
- Use of Propofol increases the healthcare cost of performing GI endoscopy.
- Medical necessity of Propofol in GI endoscopy estimated to be 10-20% but Propofol gaining in popularity in some markets.
- Clinical criteria: Abdominal surgery w/adhesions; BMI >35; co-morbidity.
- SEDASYS™ CAPS intends to replace the need of CRNA or anesthesiologist (in GI endoscopy).
- Awaiting FDA approval.
- Price, cost, billable charge (facility vs. pro)?

Investigational CAPS Device

Procedure Room Unit

Bedside Monitoring Unit with Patient Monitoring

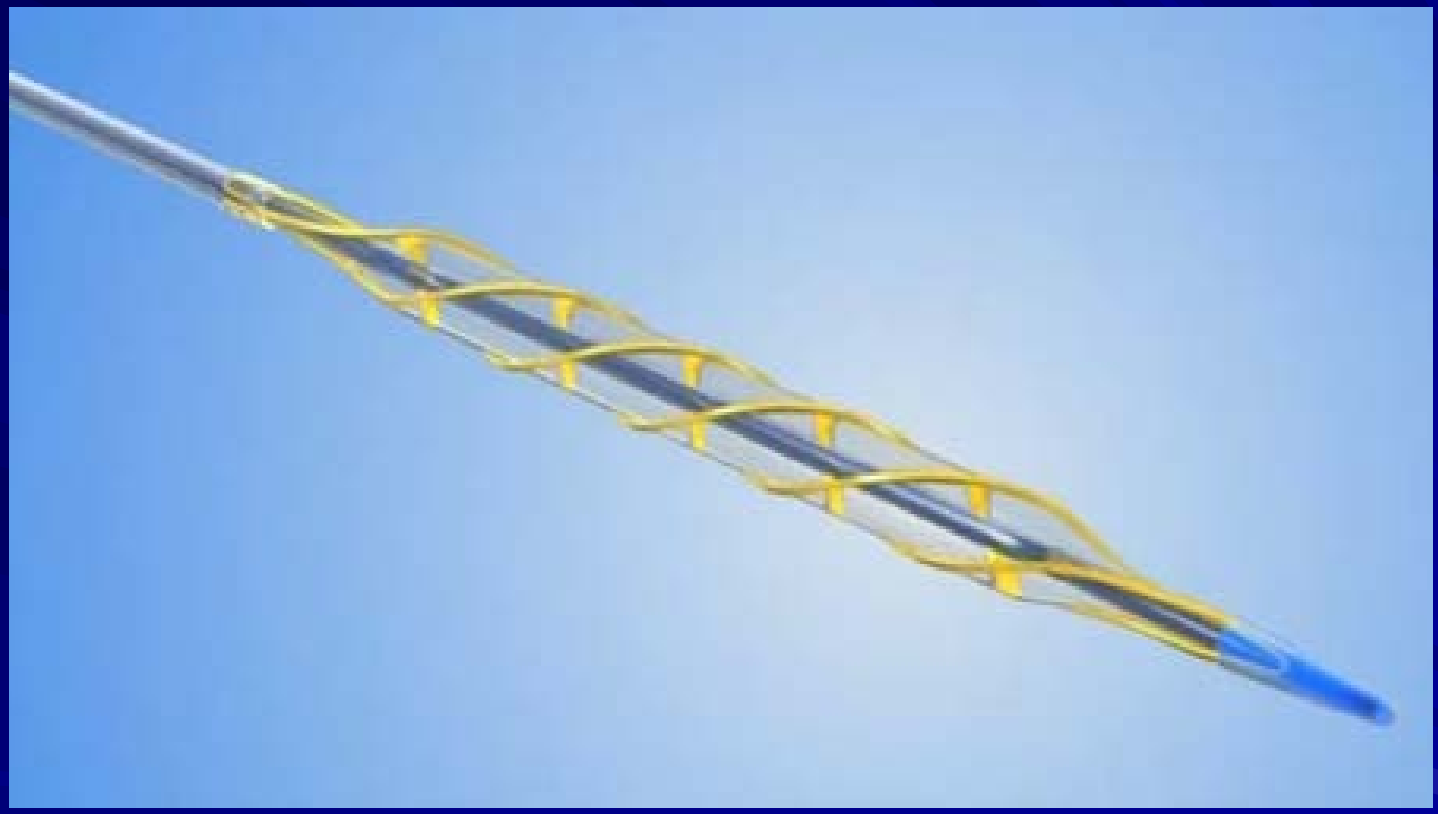
Investigational device limited by U.S. law to investigational use only

SEDASYS – for Propofol & MAC (update)

- Anesthesia – topical, local, regional/block, moderate (conscious) sedation, deep sedation (MAC), general anesthesia.
- 2011 update –
  - Ethicon (J&J) PMA filed – expedited review from FDA
  - Strong recommendation (8-2) for approval from FDA's Anesthesiology and Respiratory Therapy Devices Advisory Committee
  - However, FDA's Center for Device & Radiologic Health issued letter of non-approval in early 2010
  - Then, FDA Commissioner's Office in Oct. 2010 granted Ethicon an appeal for new independent advisory committee review
- What if MJ's physician had this machine?

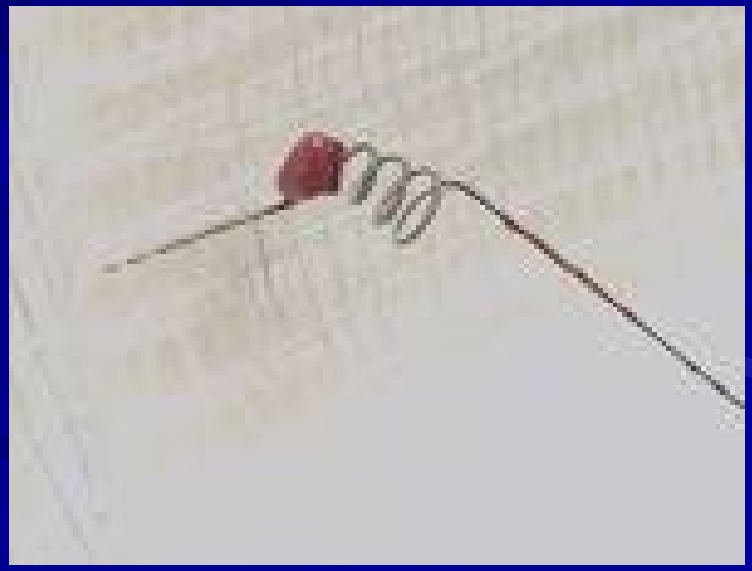
AngioSculpt Scoring Balloon Catheter (AngioScore, Inc.)

- Double-lumen catheter with scoring balloon near distal tip. Balloon inflation w/contrast and guidewire advancement to stenotic lesion.
- FDA-approved for PAD, but not CAD.
- Projected device cost ~ $900 + pro fee + facility
- CPT 3547x, 7596x, 7597x
- ICD-9 39.50
- Usually inpatient – DRG 479, 553, 554
- OPPS – APC 081
- Percutaneous transluminal angioplasty of PA considered investigational by many health plans and payers.
- FDA approval for CAD forthcoming?



MERCI Retrieval System
(Concentric Medical, Inc.)

- Mechanical Embolus Removal in Cerebral Ischemia (MERCI).
- Nitinol cork screw wire catheter device – embolus retrieval in acute embolic stroke.
- FDA-approved. NIH recruting, conducting additional clinical trial.
- Projected device cost ~ $6500 + pro fee + facility
- Considered investigational by many payers
- CPT 34001, 34051, 36215-36218, 756xx, 37184, 37185
- ICD-9 39.74
- DRG – 1, 2, 543



MEG / MSI

- Magnetoencepholography
  - Records magnetic forces associated with the electrical activity of the brain externally on the scalp.
  - Recorded data are analyzed to provide an estimated location of the electrical activity using mathematical modeling.
- Magnetic Source Imaging
  - Functional mapping of MEG with MRI.
- Unlike EEG (electroencephalogram), magnetic fields are not altered by surrounding brain structures.
- Greater accuracy due to the minimal signal distortion and provides more usable and reliable localization of brain function.
- Many payers consider MEG/MSI investigational.
- CPT 95966, 95977; plus 9295x and 7055x

Cardiology: EECP for Angina & CHF

- Enhanced External Counterpulsation (EECP) may stimulate the openings or formation of collaterals (small branches of blood vessels) to create a natural bypass around narrowed or blocked arteries.

- EECP is considered **investigational** for the treatment of congestive heart failure or chronic stable angina pectoris by many health plans/pay

  - HCPCS code G0166 = denied service
    - **external counterpulsation, per treatment session**

  - CPT code 92971 = payable service
    - **cardioassist-method of circulatory assist; external**
    - **allowed amount = ~ $120 per session / $4200 per tx episode**

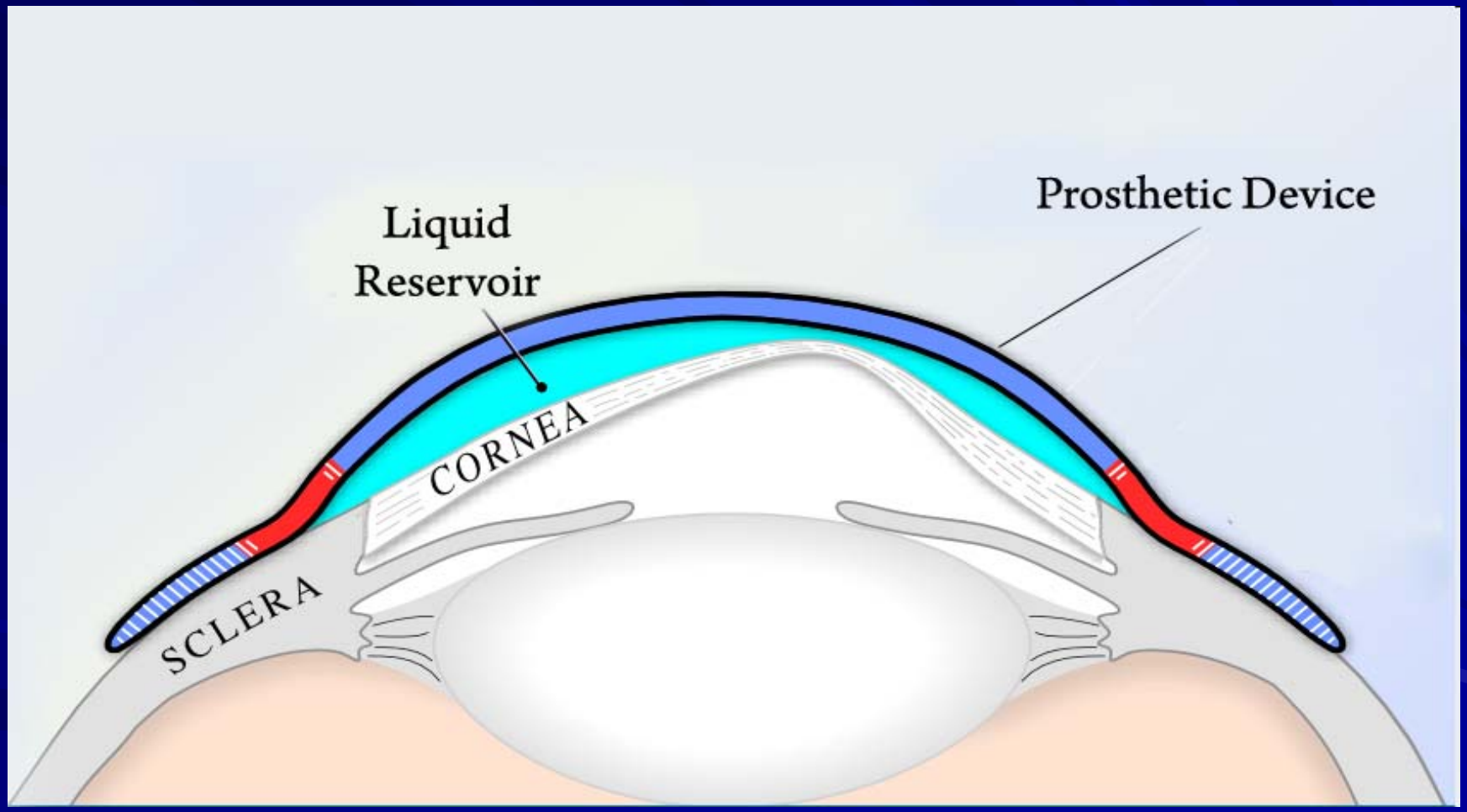
Balloon Sinuplasty

- Endoscopic flexible balloon catheter system for sinusitis.
- FDA 510(K) marketing clearance.
- No clinical outcomes data in FDA clearance summary. Scant published scientific evidence.
- Outpatient procedure performed under sedation anesthesia.
- Touted as cross between medication tx and endoscopic sinus surgery.
- Considered investigational by many payers.
- S2344, 31295, 31296, 31297 = denied service.
- 31256, 31276, 31287 = payable service. $260-$580

Prosthetic Replacement Ocular Surface Ecosystem (PROSE)

- Not a surgical eye implant – *aka* Boston Scleral Lens or BOS-P – Boston Foundation
- Special type of contact lens for corneal conditions – keratoconus, Sjoren's, CGVHD
- 8 centers (Boston, NY, TX, IL, MI, CA)
- CPT 92499 – unlisted ophthalmological service or procedure / billed charges = $15K
- V2627 - Scleral cover shell / billed charge $4,400

PROSE / BOS-P



Doc#[redacted]

Subscriber
[redacted]
Date of Birth [redacted]
Sex M

Subscriber ID
[redacted]

Patient
[redacted]
Date of Birth [redacted]
Sex M
Relationship 18(Self)

Condition Date None
Accident Indicator (blank)
Worker's Comp Indicator (blank)
Admission Date (none)
Discharge Date (none)
ACM claim number none

Billing Provider
USC CARE MEDICAL GROUP INC
FILE 50938
LOS ANGELES CA 900740938

Assigned PIN#: [redacted]
TIN#: [redacted]
SSN#: none
Blue Shield PIN#: none
NPI#: [redacted]
Other #s: none

Service Location
USC OPHTHALMOLOGY LOS ANG
1450 SAN PABLO ST
LOS ANGELES CA 90033

Referring Provider
[redacted]

Pay To Provider
None

Medicare Assignment A(Assigned)
Patient Account # [redacted]
Medical Record # None
Prior Authorization Number # None
Contact phone # None

Other Insurance

T	Payor name / Subscriber Name	Subscriber #	Sex/Rel	Group #	DOB	Code Value
P	BLANK [redacted]	BLANK	M/21 (Unknown)	BLANK	[redacted]	

Claim

Note: 10107

DX1 371.60
DX2 V42.5
DX3 367.22
DX4 371.00

#	Date Of Service	Pos T	Proc Code	Dx Value	Charge	Uos	Performing Provider
1.	03/31/10-03/31/10	11	92499-LT-RT	1234	$15000.00	2	BLANK BLANK NPI#: [redacted]
2.	03/31/10-03/31/10	11	V2627-LT-RT	1234	$4400.00	2	BLANK BLANK NPI#: [redacted]
					$19400.00		

Complete 837 Detail

Prosthetic Replacement Ocular Surface Ecosystem (PROSE)

- CPT 92317 – medical supervision and fitting of corneoscleral lens fitting (correct code; not billed)

- Boston scleral lens - $4,400 (V2627)
- Special lens fitting - $500 (92499)
- 92925 – computerized corneal topography

FeNO – Exhaled Nitric Oxide

- Fractional expiration of NO levels
- Exhaled NO = biomarker for airway inflammation
  - Chemiluminescence analysis: NO concentration in gaseous phase by reacting NO in sample with O_3 to produce NO_2 in excited state. Research setting / expensive.
- POS measurement of airway inflammation
  - NIOX FeNO handheld unit
- Overall low-moderate quality evidence. ATS 2011
  - 2 RCTs (Selzer et al 2008/Shaw et al 2007) not favorable
  - 2011 Australian RCT (Powell et al) favorable
- 95012 - Nitric oxide expired gas determination - $30

Bronchial Thermoplasty

- C9730, C9731- Bronchoscopic bronchial thermoplasty with imaging guidance (if performed), radiofrequency ablation of airway smooth muscle
  - New minimally invasive approach to treat refractory asthma; limited studies.
  - Investigational by most major payers
- 31641 – bronchoscopy; destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)

Coronary CTA & Ca^{++} Scoring

- 75571 - Cardiac CT, w/o contrast, with quantitative evaluation of coronary calcium
  - Investigational for coronary ♥ disease risk score
- 75572 - Cardiac CT, w/contrast
- 75573 - Cardiac CT, w/contrast; congenital HD
- 75574 - Coronary CT angiography, w/contrast & 3D; coronary artery, bypass graft, morphology
  - Covered for R/O MI in chest pain of low PTP
  - POS 23, 22, 24, 21 vs POS 11, 20
- Ultrafast EB CT vs Helical/Spiral MDCT (64-320)

Fusion Scans

- 78814-78816: PET w/concurrently acquired CT scan for attenuation correction and anatomical localization
  - include both PET scan and concurrent CT scan for attenuation and anatomical localization
  - CT scan (e.g., 71260) not separately billable unless separate & distinct diagnostic service
  - NCCI allows CT scans (71260 & others) to be billed with 78814-78816 – claims system/CC does not stop
  - Beware of abuse!
  - CPT: Modifier-59 allowed if separate & distinct dx procedure

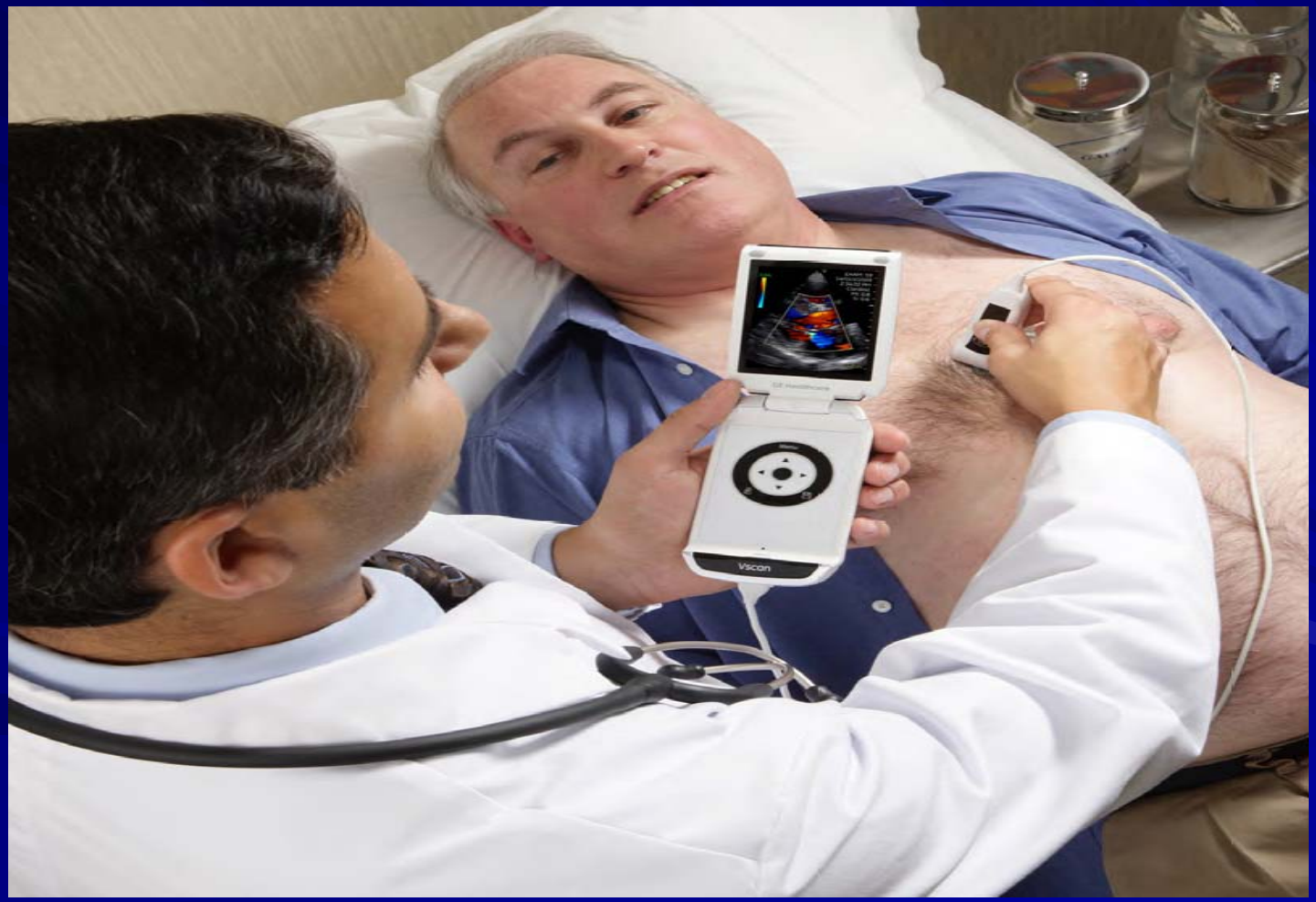
Fusion Scans

- If CT scan (e.g., 71260) is billed without modifier 59 to denote separate & distinct diagnostic CT scan from 78814-78816, it (e.g., 71260) should be denied.
  - Caveat: may be necessary to customize your CC
- If CT scan is billed with modifier-59 (e.g., 71260-59) to denote separate & distinct diagnostic CT scan from 78814-78816, it (e.g., 7126059) may be allowed.

Fusion Scans

". . . the CT portion of this code series (78814-78816) is used for the purposes of attenuation correction and for anatomical localization when performed concurrently with PET imaging. It is important to note that if a diagnostic CT is performed concurrently with the PET study and separate orders, which are medically necessary, are provided, then the CT portion will be used two fold. First, it will be used as previously noted for the purposes of attenuation correction and anatomic localization. Additionally, it will be used to obtain a fully diagnostic and reportable CT scan. In this case, providers should use the appropriate code from the 78814- 78816 code series to report the PET or CT procedure and also **report separately for the diagnostic CT scan with modifier *59, Distinct procedural service,* appended to the CT code for the appropriate anatomical area**." (*CPT 2005*)

Portable Ultrasound / Echocardiogram



Portable Ultrasound / Echocardiogram

Portable Ultrasound / Echocardiogram

- Retails $7,900 / sold only to licensed MD
- Echocardiogram (cardiac ultrasound)
- Obstetric / Fetal ultrasound
- Liver ultrasound
- Kidney ultrasound
- Ultrasound Image Guidance
- IGRT / IMRT !?

Portable Ultrasound / Echocardiogram

- 93303, 93304 – echocardiogram
- 76801, 76802, etc – Ob / Fetal US
- 76942 – US guidance for needle placement
  - Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
- 10022 – imaging guidance FNA

H I F U

H I F U

High Intensity Focused Ultrasound (HIFU)

- Noninvasive system – high-intensity ultrasonic beam to heat treat prostate cancer, uterine fibroids, endometriosis, etc.
- Sonablate 500 & Ablatherm® HIFU for localized prostate ca
- Fairly widely used in Europe and Canada
- Also investigated for use in hepatic, pancreatic, breast, renal, and bone cancers
- No US-HIFU has FDA approval in US currently
- ExAblate – FDA approved 2004 – MRgFUS
- No CPT or HCPCS
  - 77600, 77605, 77610, 77615, 77620 (Hyperthermia Tx)
  - $550-$1,350 professional

Autonomic Nervous System Testing

Visceral/involuntary controls: heart rate, respiration, perspiration, salivation, etc.

- 95921 - heart rate response to deep breathing with recorded R-R interval, Valsalva ratio ($101)
- 95922 - beat-to-beat blood pressure and R-R interval changes during Valsalva maneuver ($127)
- 95923 - quantitative sudomotor axon reflex test (QSART), silastic sweat imprint, thermoregulatory sweat test, and changes in sympathetic skin potential ($193)
- Medical Policy? Payment edits?
- 337.20-337.29

Autonomic Nervous System Testing

HydroStat Hydrogen Breath Tester™

Company's marketing verbiage –

- *Improves patient care and outcomes by diagnosing small intestinal bacterial overgrowth, fructose malabsorption, and lactose intolerance*
- *Provides complete system of treatment with seamless practice integration*
- *Includes treatment protocols, customized patient awareness tools and educational handouts*

HydroStat Hydrogen Breath Tester™

- *CLIA exempt - No special certification or licensing is required; any staff member can administer*
- *Profitable: The HydroStat is covered by Medicare, Medicaid, and virtually all private and managed care insurance plans*
- 91065 - Breath hydrogen test (eg, for detection of lactase deficiency, fructose intolerance, bacterial overgrowth, or oro-cecal gastrointestinal transit)
  - $110 fee schedule

HydroStat Hydrogen Breath Tester™

SIBO & Hydrogen Breath Test

- Hydrogen Breath Test used in dx of SIBO
- How to detect potential F&A –
  - Fasting for at least 12 hours required prior to test.
  - At the start of the test, the patient blows into and fills a balloon with a breath of air.
  - Concentration of hydrogen is measured in a sample of breath removed from the balloon. The patient then ingests a small amount of the test sugar (lactose, sucrose, sorbitol, fructose, lactulose, etc. depending on the purpose of the test).
  - Additional samples of breath collected and analyzed for hydrogen every 15 minutes for three and up to five hours.

Oncimmune EarlyCDT™ Lung Test

- Physician-ordered blood test
- Marketed as early lung cancer detection by measuring immune response to antigens produced by solid-tumor cells in the form of autoantibodies (or immuno-biomarkers)
- Lab bills 83520 - Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified / 7 units
- Aetna Med Policy (2011) – investigational
  - Test lacks support for sufficient sensitivity/specificity

Provent® Sleep Apnea Therapy

- Marketed as “sleep apnea treatment without CPAP” – a CPAP alternative
- “clinically proven obstructive sleep apnea treatment effective for mild, moderate, and severe OSA”
- Also market as therapy for snoring
- Aetna Medical Policy (2011) – investigational
- Nasal Expiratory Resistance Device
  - E1399 (misc. DME) x 30 units

Provent® Sleep Apnea Therapy

BART

Large genomic rearrangements occur in a small percentage (<1%) of all patients tested for hereditary breast and ovarian cancer. In August 2002, Myriad launched an enhancement to the BRAC*Analysis* test to detect five common large rearrangements. The BRAC*Analysis* Rearrangement Test, or BART, launched in August 2006, is designed to detect large rearrangements beyond these five.

BART

- Intended for highest-risk patients tested negative with complete *BRCA1 & BRCA2*
  - Breast ca <50 yo + 2 relatives <50 &/or ovarian ca
  - Ovarian ca + 2 relatives <50 &/or ovarian ca
  - Male breast ca + 2 relatives <50 &/or ovarian ca
  - Breast ca ≥50 & ovarian ca + 1 relative
  - Breast ca <50 & ovarian ca
- BART will automatically be performed *concurrently* with complete *BRCA* gene sequence analysis for high-risk (typically no additional charge)

BART

- 83891 - Molecular diagnostics; isolation or extraction of highly purified DNA or RNA
- 83898 - Molecular diagnostics; target amplification, each DNA or RNA sequence
- 83909 - Molecular diagnostics; separation and identification by high resolution technique (eg, capillary electrophoresis), each nucleic acid preparation
- 83912 - Molecular diagnostics; interpretation & report

FAQ on Lab's own website

For patients that meet the clinical criteria, how do I order BART?

- Completely fill out the clinical history section of the Test Request Form (TRF). If the clinical criteria are met, BART will automatically be performed concurrently with comprehensive BRAC*Analysis*.

Oncotype DX

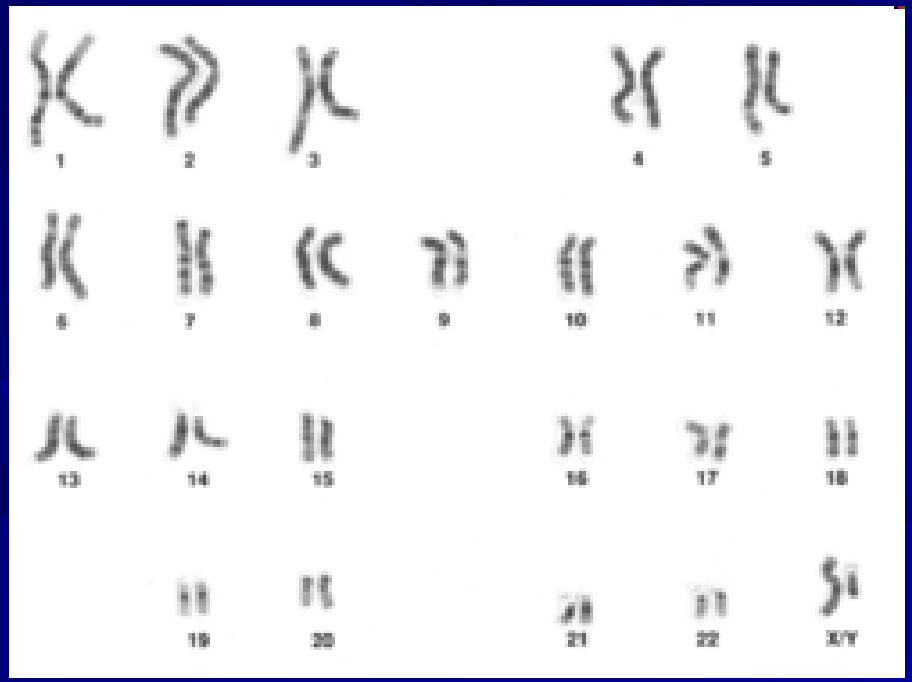
- Oncotype DX - Breast
  - 21-gene RT-PCR assay covered by most payers for medically necessary (node-/ER+/HER2-) assessment of adjuvant chemoRx in recently-dx breast cancer
  - HCPCS S3854 - gene expression profiling Br CA
- Oncotype DX - Colon
  - 12-gene RT-PCR assay not covered
  - CPT 84999 - unlisted chemistry procedure

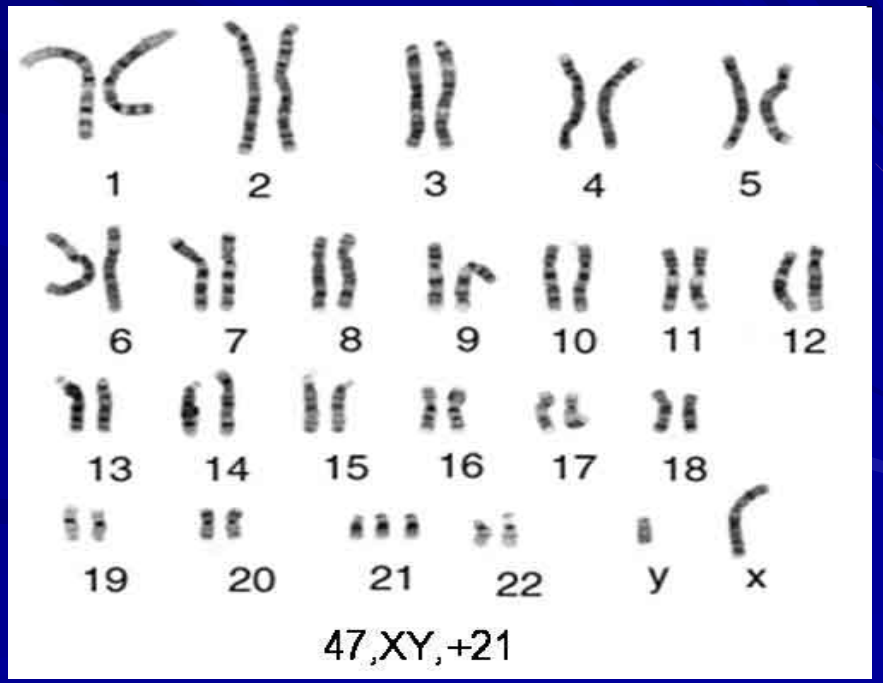
Molecular Cytogenetic Testing

- Genetic variations are basis for genetic disorders and developmental delay.
- Standard cytogenetic analysis detects visible chromosomal alterations, such as extra chromosome bands, but smaller defects difficult to detect.
- Evolution of Genetic Testing –
  - Chromosomal Banding – Karyotyping: older cytogenetics
  - Fluorescent *in situ* Hybridization (FISH): newer DNA cytogenetic method
  - Comparative Genomic Hybridization (cGH) or Chromosomal Microarray Analysis (CMA): newest DNA cytogenetic method

Chromosomal Banding - Karyotyping

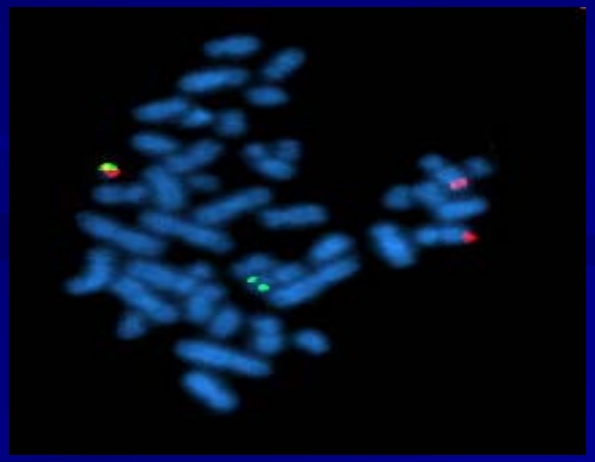
- **Karyotype** – number and appearance of chromosomes in the nucleus of a cell under light microscope: length, position of centromeres, banding pattern, etc.
- CPT 88261-88285

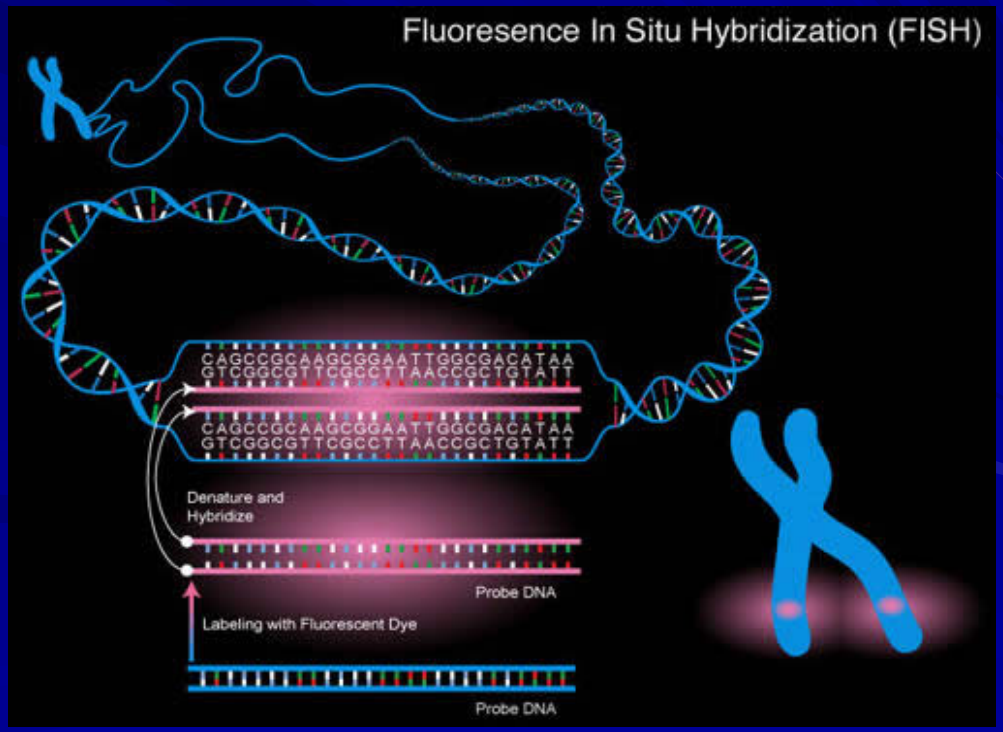




F I S H

- Detect the presence or absence of specific DNA sequences on chromosomes
- Fluorescent DNA probes bind to parts of chromosome of high degree of sequence complementarity
  - Fluorescent microscopy
  - Genetic Counseling
  - 88120,88121,88271,88365-8

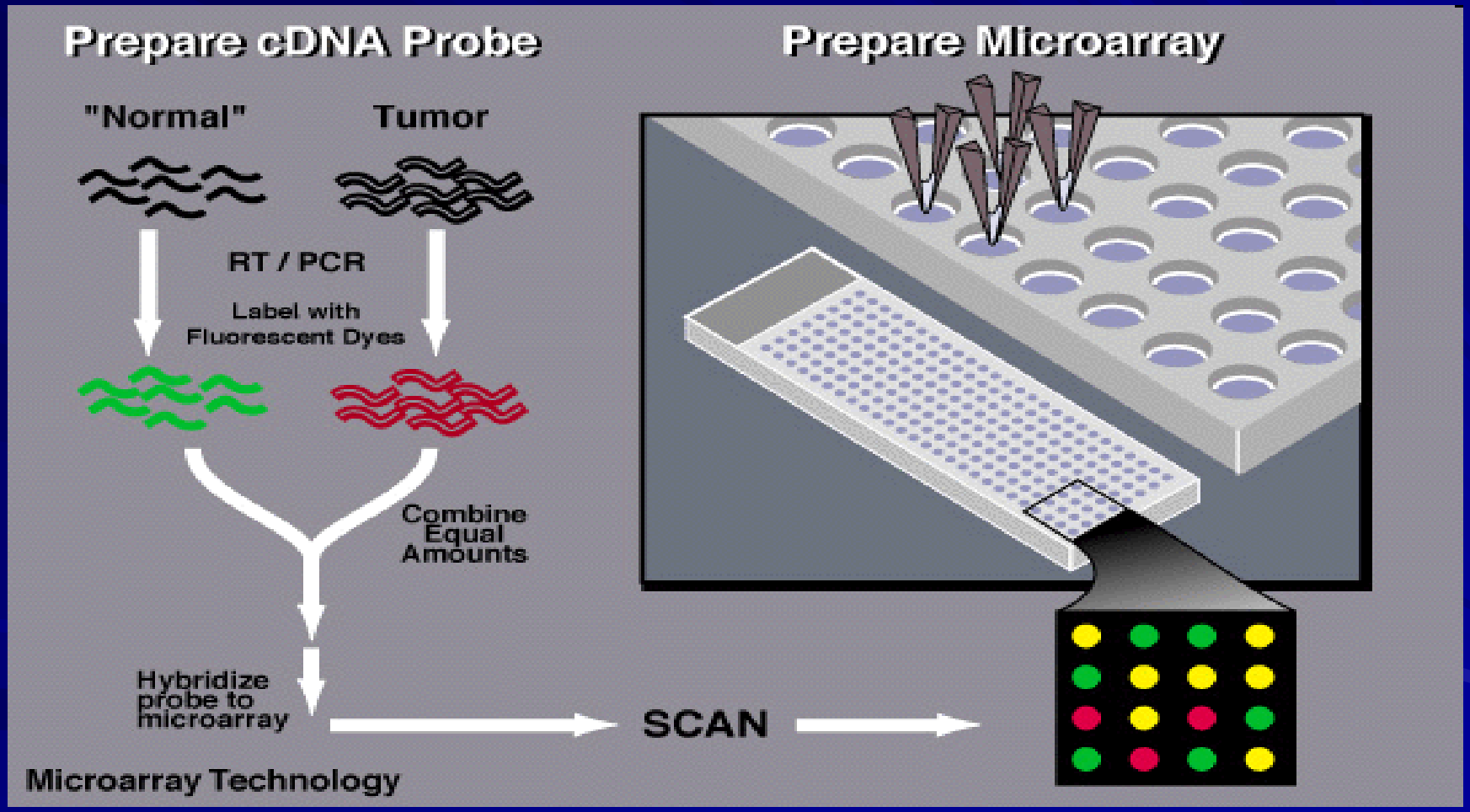




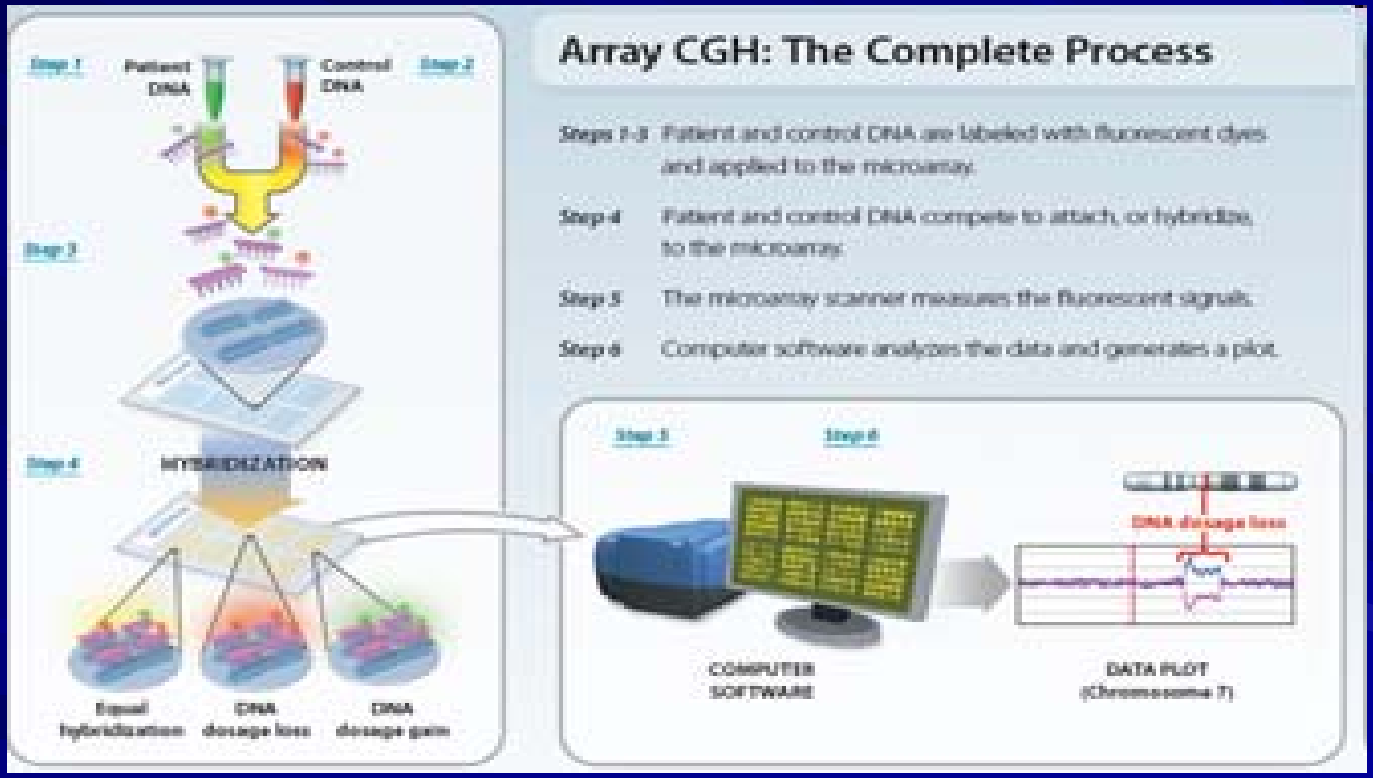
Chromosomal Microarray Analysis (CMA) Comparative Genomic Hybridization (cGH)

- Detects cytogenetic imbalances smaller than possible with other available chromo analysis: High Resolution
- DNA probes as arrays to hybridize a differentially labeled patient and normal DNA – to identify changes throughout genome.
- Arrays arranged to correspond to genes known to affect development. cGH detects loss or duplication of chromosomes on the array.
- High Resolution Genetic Testing / Study DNA in tumors
- S3870 - cGH microarray testing for developmental delay, autism spectrum disorder, mental retardation

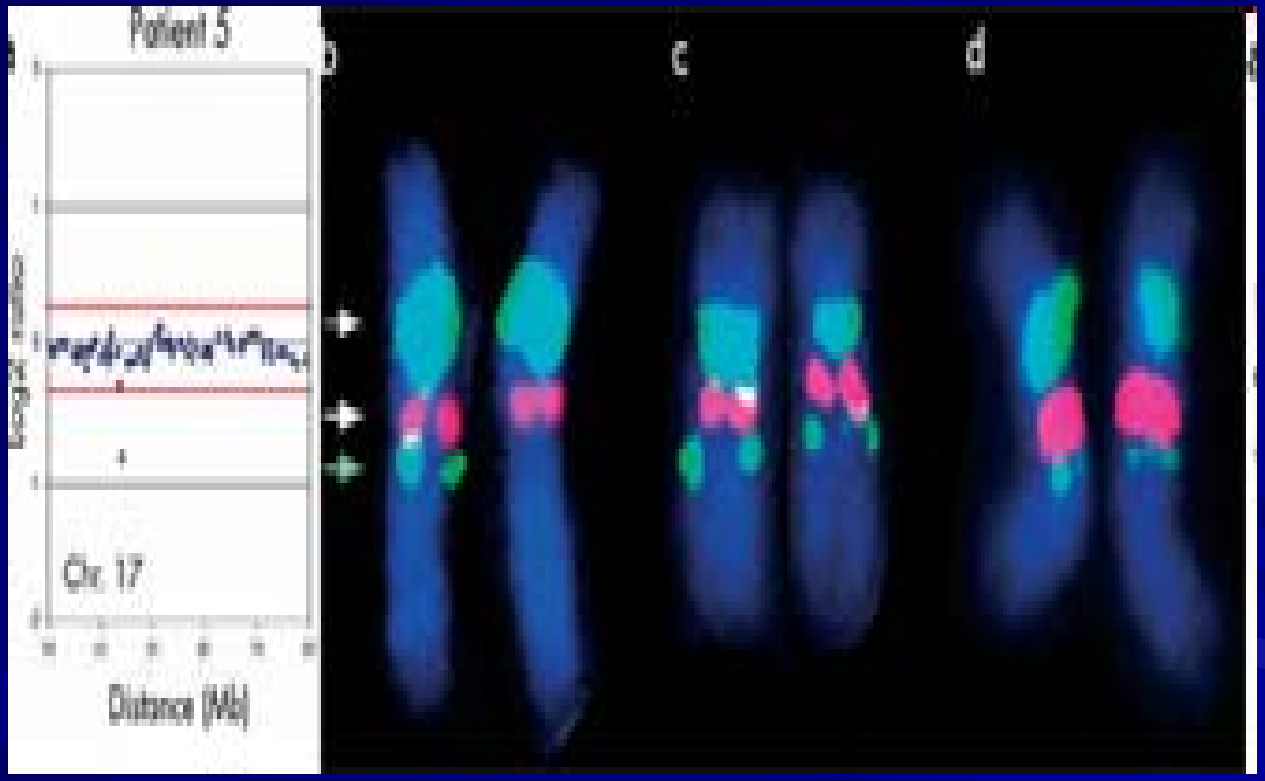
Array cGH / CMA



Array cGH / CMA



Array cGH / CMA



Targeted Biologics
Targeted Therapeutics
Genomics
Theragnostics

The application of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, and help determine a person's predisposition to a particular disease or condition

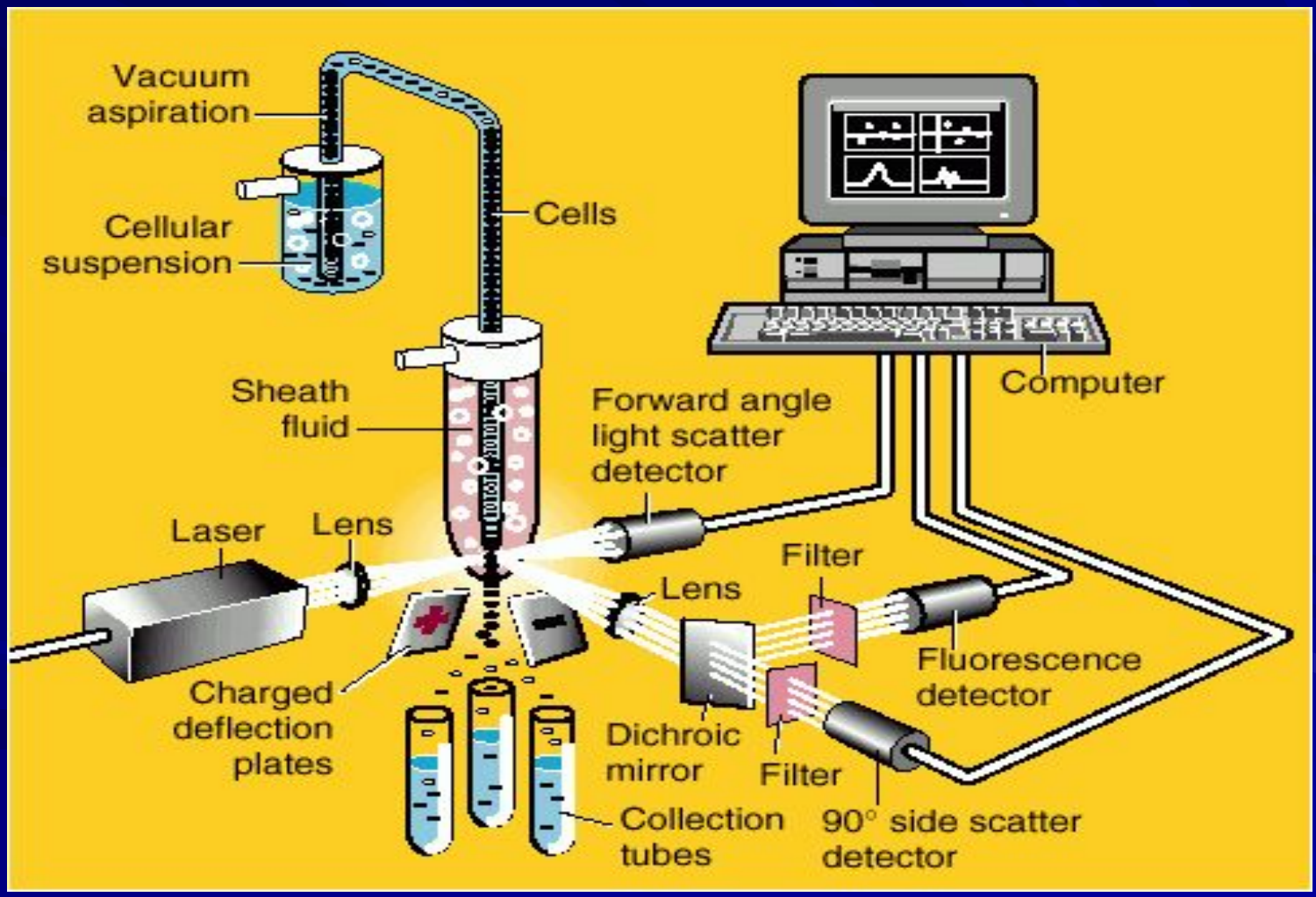
Lab: Companion Diagnostics

Drug	Indication	Biomarker	Companion Dx
Maraviroc (Selzentry)	HIV / AIDS	CCR5 co-receptor	Trofile DNA 87901, 87999
Imatinib (Gleevec)	CML	BCR-ACL kinase	BCR-ACL mutation 83891, 83902, 83898, 83904, 83912
Trastuzumab (Herceptin)	Breast Cancer	HER2	HER2 receptor-FISH 88342,88360,88361,88365
Cetuximab Panitumumab	Colon Cancer	KRAS	KRAS mutation-FISH 88342,88360,88361,88365
Crizotinib (Xalkori)	NSCLC	ALK fusion proteins	Vysis ALK Break Apart FISH Probe Kit - 88367,88368
Vemurafenib (Zelboraf)	Malignant Melanoma	BRAF V600 mutation	Cobas RT-PCR - 83907, 83891,83892,83898, 83896, 88381, 83914, 83912-26

Flow Cytometry

- Characterization and measurement of cells and cellular constituents
- Fluorescent-labeled cells suspended in fluid and passed through focused light
  - sensor detects the scattered or emitted light measures the size and molecular characteristics of individual cells; tens of thousands of cells can be examined per minute and the data gathered are processed by computer
- 88182, 88184, **88185**, 88187, 88188, 88189
  - Flow cytometry – cell surface, DNA analysis, cytoplasmic or nuclear marker
  - MUE issue

Flow Cytometry



Questions?

Thank you!

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