

Infusion Therapy for the Facility

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Disclaimer

- This presentation was current at the time of submission
- Updates to this topic will be incorporated at the time of presentation as much as possible.
- Presenter has no affiliation with any commercial entity regarding this topic
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Educational Goals for Session

- The attendee will have a working understanding of the various types of infusion therapy and services inherent to them.
- The attendee will have a working understanding of the infusion therapy code hierarchy per CPT and CMS for Facility
- Documentation of Infusions for Compliance will be addressed and a Form provided
- Federal Guidelines for Infusions will be covered.

Facility vs. Professional

- UB02
- Code hierarchy based on CPT directions
Chemo, Therapeutic, Hydration
- Rev Codes
- CPT Codes
- ICD 9CM Codes
- Pharmacy Bills drugs
- CMS 1500
- Code based on reason for visit
- CPT codes
- ICD9 CM Codes
- Can only code drugs if physician buys them from the pharmacy
- Incident to in the office

Facility Coding and Billing

- Charge Master
- Rev Codes
- Pharmacy
- Central Supply
 - Charge Capture
- Overhead
- Staff

Drugs

- Pharmacy does the mixing
- Pharmacy Supplies
- Pharmacy gets a copy of the orders
- Pharmacy does the coding/billing
- Billing from Pharmacy joined with all other facility charges to drive APCs

Pharmacy Rev Codes

- *025X Pharmacy*
- *Code indicates charges for medication*

IV Therapy

- *026X IV Therapy*
- *Code indicates the administration of intravenous solution by specially trained personnel to individuals requiring such treatment.*

063X Pharmacy - Extension of 025X

Code indicates charges for drugs and biologicals requiring specific identification as required by the payer. If HCPCS is used to describe the drug, enter the HCPCS code in FL

063X Pharmacy - Extension of 025X

- ***Subcategory 0 - RESERVED (Effective 1/1/98)** 1 - Single Source Drug 2 - Multiple Source Drug 3 - Restrictive Prescription 4 - Erythropoietin (EPO) less than 10,000 units 5 - Erythropoietin (EPO) 10,000 or more units 6 - Drugs Requiring Detailed Coding*
- *7 - Self-administrable Drugs*

063X

- **NOTE:** (a) *Charges for drugs and biologicals (with the exception of radiopharmaceuticals, which are reported under Revenue Codes 0343 and 0344) requiring specific identifications as required by the payer (effective 10/1/04).*
- *If HCPCs are used to describe the drug, enter the HCPCS code in Form Locator 44. The specified units of service to be reported are to be in hundreds (100s) rounded to the nearest hundred (no decimal).*

Supervision

- The definitions of the supervision levels and other supervision requirements are delineated in 42 CFR 410.27 and the Medicare Benefit Policy Manual (Pub. 100-02) Chapter 6, Sections 20.5 - 20.7.
- http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CM-S-1525-FC_FINAL_2012_Extended_Duration_Services.pdf

Supervision

- The physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen.
- “Personal supervision” means the definition specified at 42 CFR 410.32(b)(3)(iii), that is, the physician must be in attendance in the room during the performance of the service or procedure.

Types of Supervision

- Direct - “direct supervision” means that the physician or nonphysician practitioner must be present on the same campus where the services are being furnished.
- General-“general supervision” means the definition specified at 42 CFR 410.32(b)(3)(i), that is, the procedure or service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure.
- **“Non-Surgical Extended Duration Therapeutic Services”= NSEDTS**

Extended Duration Services

- Most therapeutic and chemotherapeutic services.
 - Services require long period of time to provide
 - Services require intense supervision.
- Services have a low risk of requiring the supervisory practitioner's immediate availability to furnish assistance and direction after the initiation of the service

New List in Effect 01/2013

- CMS requires a minimum of direct supervision during the initiation of the service which may be followed by general supervision for the remainder of the service at the discretion of the supervisory practitioner.
- “Initiation” means the beginning portion of the extended duration service, ending when the supervisory practitioner believes the patient is stable enough for the remainder of the service to be safely administered under general supervision.

Documentation

- The point of transition to general supervision must be documented in the patient's progress notes or medical record.
- The manner of documentation is otherwise at the discretion of each supervisory practitioner.

What is Infusion Therapy?

- Infuse
 - Delivery of drugs and/or fluids through a non-oral route.
 - Most often through a vein using a needle and/or a catheter.
 - Continuous slow introduction of fluids through other routes are also common.
- Therapy
 - Treatment to effect a cure for a disease or disorder

Routes

- What are all the ways to infuse medications and fluids into the human body?
- Does infusion only happen in a vein?

Injectiions

- **Injection: forceful direct introduction of a drug or other fluid into the bloodstream or body tissues.**
- **Infusion: delivers fluid (such as hydration for the protection of renal function), into a vessel or anatomic space maintaining fluid balance and/or adding medications or nutrients.**

Tools of the Trade!

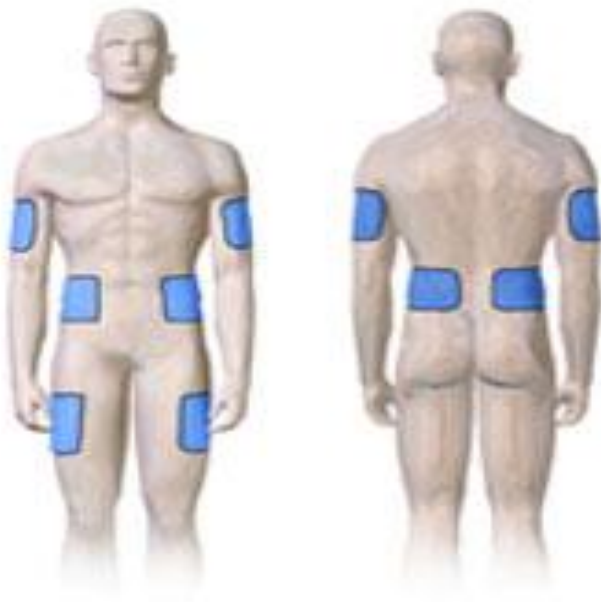


Parts of a Syringe

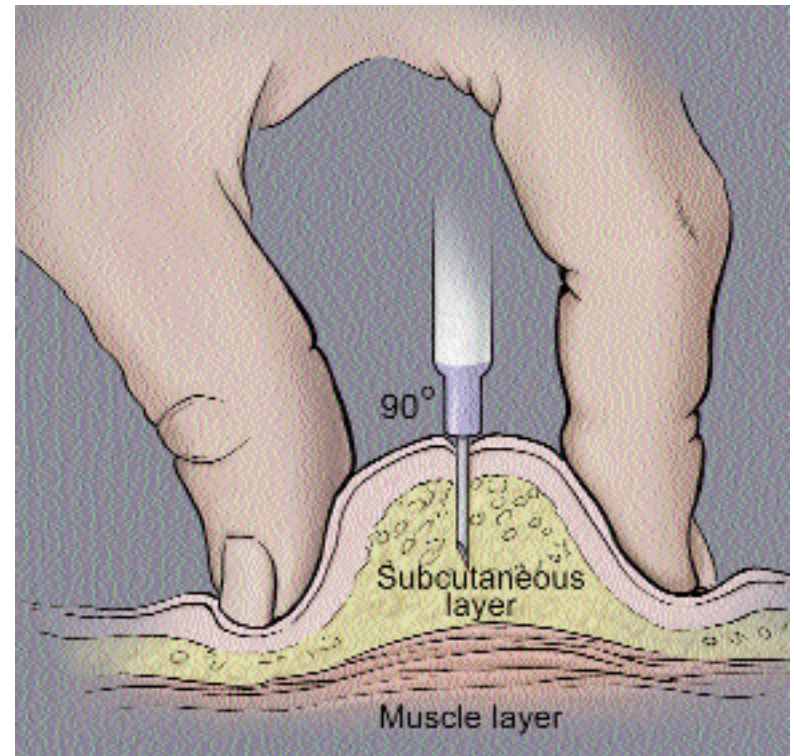
SQ Injections 96372

- A subcutaneous injection is administered just under the skin in the fatty tissue of the abdomen, upper arm, upper leg, or buttocks.
 - The skin is cleansed.
 - A two-inch fold of skin is pinched between the thumb and forefinger.
 - The needle is inserted completely under the skin at a 45 to 90 degree angle using a quick, sharp thrust.
 - The plunger is retracted to check for blood.
 - If blood is present, a new site is selected.
 - If no blood is present, the medication is injected slowly into the tissue. The needle is withdrawn and mild pressure is applied.

SQ Injection Technique



Sites on the Body Where
a Subcutaneous Injection
Can Be Given



Therapeutic, Prophylactic, and Diagnostic Injections

- **96370 Subcutaneous infusion** for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
- **96371 Subcutaneous infusion** for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of **new subcutaneous infusion site(s)** (List separately in addition to code for primary procedure)

Intralesional Chemotherapy

96405 Chemotherapy administration,

intralesional; up to and including 7 lesions

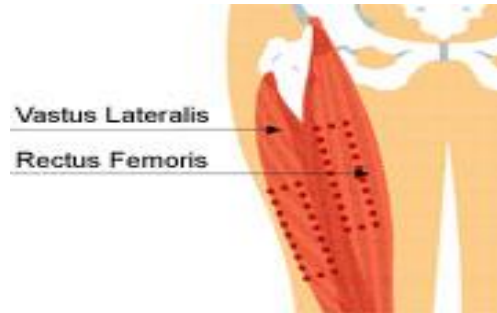
96406 ... more than 7 lesions

IM Injection 96372

- An intramuscular injection is administered in a similar fashion deep into muscle tissue, differing only in the sites of administration and the angle of needle insertion. The angle of insertion is 90 degrees.
- Intramuscular administration provides rapid systemic absorption and can be used for administration of relatively large doses of medication.
- Must document site.

IM Injection Technique

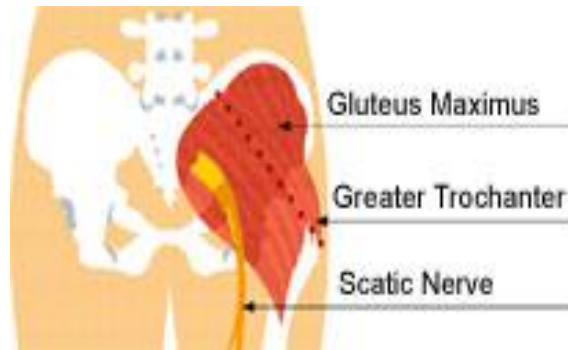
Giving an IM injection into the Vastus lateralis site



- To find the thigh injection site, make an imaginary box on the upper leg. Find the groin. One hand's width below the groin becomes the upper border of the box
- Find the top of knee. One hand's width above the top of the knee becomes the lower border of the box
- Stretch the skin to make it tight
- Insert the needle at a right angle to the skin (90°) straight in
- Up to 2ml of fluid may be given into this site

IM Injection Technique

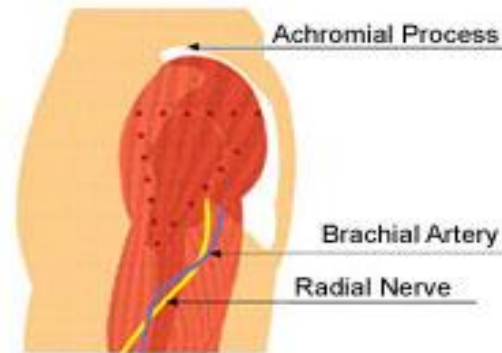
IM injection into the Gluteus medius site (buttock)



- Find the trochanter. It is the knobby top portion of the long bone in the upper leg (femur). It is the size of a golf ball
- Find the posterior iliac crest. Many people have 'dimples' over this bone
- Draw an imaginary line between the two bones
- After locating the centre of the imaginary line, find a point one inch toward the head. This is where (X) to insert the needle
- Stretch the skin tight
- Hold the syringe like a pencil or dart. Insert the needle at a right angle to the skin
- Up to 3ml of fluid can be given in this site

IM Injection Technique

Giving an IM injection into the deltoid site



- Find the knobby top of the arm (acromion process)
- The top border of an inverted triangle is two finger widths down from the acromion process
- Stretch the skin and then bunch up the muscle
- Insert the needle at a right angle to the skin in the centre of the inverted triangle

Caution: This is a small site – give only 1-2ml or less of fluid in this site

IV Push

- Delivery of drugs and other solutions using an IV push technique is considered an injection instead of an infusion.
 - Also call a “bolus” of medication.

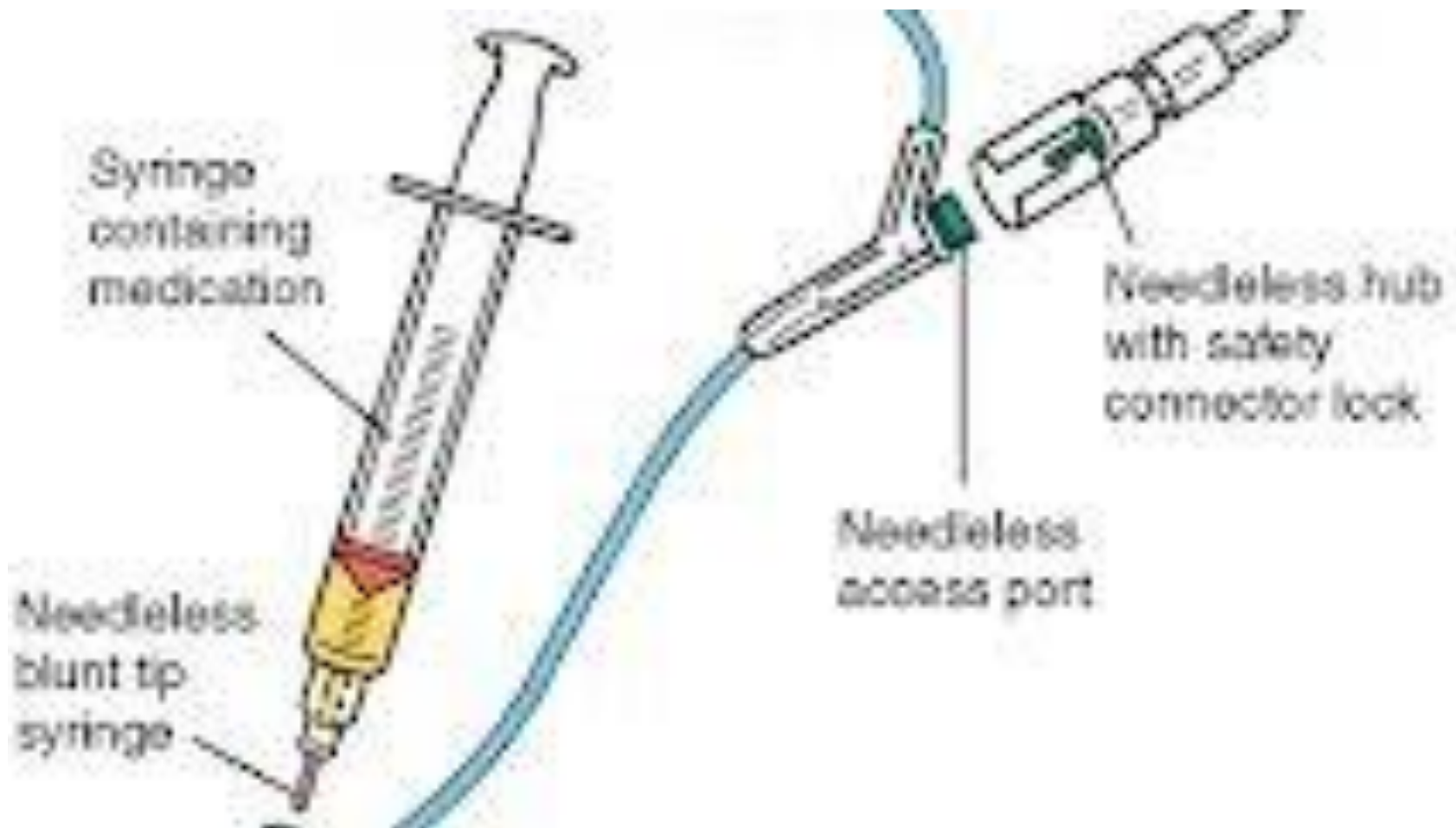
IV Push Technique 96374

- Method of administering a medication directly into a vein or artery using a syringe and needle or butterfly needle
- Can administer medications through existing IV line
 - Usually takes less than 15 minutes
 - Volume usually under 50 ml

“Piggyback”

- When an IV Push or IV infusion is hooked into an existing Intravenous Line for the administration of medication or blood products.
- In the event that multiple Medications are mixed
 - They must be compatible
 - They share a single service CPT code.
- Modifier –59 may be required.

IV Piggy Back



IV Infusate



- When drugs are mixed or diluted in a small IV bag for infusion the infusate or diluent is considered to be a supply or part of the pharmaceutical and not separately reimbursed under CMS guidelines.

IV Infusates

Name of Infusate

- D5W = Dextrose in water
- NSS= Normal Saline Solution
- Lactated Ringers =

Uses and Descriptions

- Good generic infusate, not for Diabetics
- Physiologic Saline salt in water and is the gold standard for infusate
- Volume replacement with electrolytes Sodium, Chloride, Calcium, Lactate and Potassium

Infusion

- The administration of medication over a longer period of time, usually at a prescribed rate.
- Time involved is typically greater than 15 minutes & can require several hours.
- Permanent or temporary line
- Volume of fluid administered is usually greater than 50 ml

Intravenous Infusion

- Infusion over a period time of medications or blood/blood products
- Infusion directly into a vein
- Peripheral IV – IV site usually in the arm or hand
- Central Line – IV in a large central vein such as the subclavian or jugular vein.
 - Often used for corrosive drugs such as chemotherapy
 - A long term solution for infusion needs

Intra Arterial Infusion

- Infusion of drugs directly into the artery
- Seldom used
- Currently only approved for treatment of Liver /Colorectal Cancer
 - HAI – Hepatic Arterial Infusion – Continuous infusion of cancer fighting meds directly to the liver
 - A form of regional cancer therapy

Intra-Arterial Administration

96420 Push technique

96422 Infusion technique, up to one hour

+96423 Infusion technique, 1-8 hours, each
 additional hour

96524 Infusion technique, initiation of prolonged
 infusion (more than 8 hours), requiring the use of a
 portable or implantable pump

Regional Perfusion

- Regional (isolated) chemotherapy perfusion reported with codes for arterial infusion (96420-96425).
- Placement of arterial catheter coded separately

Regional Perfusion

36823 Insertion of arterial and venous cannula(s) for isolated extracorporeal circulation including regional chemotherapy perfusion to an extremity, with or without hyperthermia, with removal of cannula(s) and repair of arteriotomy and venotomy sites

36823

- **Complex operative procedure for patients with extremity lesions**
- **Includes dose calculation, hyperthermia, and administration of agent by injection into the perfusate and use of membrane oxygenator pump**
- **Do not report codes 96408-96425 with this code**

Extracorporeal Perfusion

- **The physician enters the skin of the extremity to position a cannula that connects an artery and a vein.**
- **This procedure allows the blood to circulate outside the body, where the chemotherapeutic substances are added.**

Intra-Arterial Pump

- Medicare medical necessity guidelines:
 - Infusion of 5-FU or 5-Fudr
 - Patients with primary hepatocellular carcinoma (155.0)
 - Patients with Duke's Class D colorectal cancer in whom the metastases are limited to the liver and where the disease is either unresectable or the patient refuses surgical excision of the tumor.

Intra-Arterial Pump

36260 Insertion of implantable intra- arterial infusion pump (e.g., for chemotherapy of liver)

36261 Revision of implanted intra-arterial infusion pump

36262 Removal of implanted intra- arterial infusion pump

Maintaining Line Patency

- Administration of fluid to maintain line patency is not infusion therapy
 - Example-To flush an intravenous line with NSS between chemotherapy agents
- Heparin Flush is incidental to infusion therapy when performed in the same session and not separately coded per NCCI.

Blood Draws

- When done at the same time as starting a peripheral IV they are bundled
- When done at the same time as accessing a central line or port this is a bundled service
- When done independently it is separately billable.

Saline

- Any saline used for the mixing or delivery of a chemotherapy drug is considered to be included in the reimbursement for the chemotherapy administration.

Other Infusion Routes

96440 Chemotherapy administration into pleural cavity, requiring **and including** thoracentesis

96445 Chemotherapy administration into peritoneal cavity, requiring **and including** peritoneocentesis

96450 Chemotherapy administration into CNS (e.g., Intrathecal), requiring **and including** spinal puncture

Intracavitary/Intrathecal

51720 Bladder instillation of anticarcinogenic agent (including detention time)

96542 Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents

Code Hierarchy

Outpatient Facility Infusion therapy

- Types of Infusions
 - Chemotherapy TRUMPS Therapeutic
 - Therapeutic, Prophylactic, and Diagnostic (TPD) TRUMP Hydration
 - Everything TRUMPS Hydration

Code Hierarchy

Outpatient Facility Infusion therapy

- Method of Drug Delivery
 - Infusions TRUMP Injections (IVP, IM, SQ)
 - IV Pushes TRUMP IM or SQ
 - Everything TRUMPS Hydration

Only 1 Initial Service

- If more than one “initial” service code is billed per day, the carrier shall deny the second initial service code **unless**
 - The patient has to come back for a separately identifiable service on the same day
 - Or has two IV lines per protocol. For these separately identifiable services, instruct the physician to report with modifier 59.

Using Hierarchy

- Code Chemo primary
- Code each addl for lower level services
- Example
 - 1 Hr. TPD Infusion = 96365 (initial)
 - 1 IVP = 96375 (each additional)

Each Additional Sequential Infusion

- Therapeutic Injections
 - 96365 - First Hour
 - 96366 - Second Hour of same drug
 - 96367 -First hour of second drug
 - 96366 – Second hour of second drug

CMS on Concurrent Infusions

- CPT includes a code for a concurrent infusion in addition to an intravenous infusion for therapy, prophylaxis or diagnosis.
- Allow only one concurrent infusion per patient per encounter.
- Do not allow payment for the concurrent infusion billed with modifier 59 unless it is provided during a second encounter on the same day with the patient and is documented in the medical record

Concurrent Infusions

- Mixing greater than one drug in an IV bag does NOT constitute a Concurrent Infusion.
- If meds in 2 separate IV bags are piggy backed into separate ports make certain this is documented.

Therapeutic Infusion

- A therapeutic, prophylactic, or diagnostic IV infusion or injection, other than hydration, is for the administration of substances/drugs.
 - The fluid used to administer the drug (s) is incidental hydration and is not separately payable.

Therapeutic Infusion

- If performed to facilitate the infusion or injection or hydration, the following services and items are included and are not separately billable:
 1. Use of local anesthesia;
 2. IV start;
 3. Access to indwelling IV, subcutaneous catheter or port;
 4. Flush at conclusion of infusion; and
 5. Standard tubing, syringes and supplies.
- Payment for the above is included in the payment for the chemotherapy administration or nonchemotherapy injection and infusion service.

Therapeutic, Prophylactic, and Diagnostic Injections

- **96365** Intravenous **infusion**, for therapy, prophylaxis, or diagnosis (specify substance or drug); **initial**, up to 1 hour
- **96366** Intravenous **infusion**, for therapy, prophylaxis, or diagnosis (specify substance or drug); **each additional hour** (List separately in addition to code for primary procedure)

Therapeutic, Prophylactic, and Diagnostic Injections

- **96367** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); **additional sequential infusion of a new drug, up to 1 hour** (List separately in addition to code for primary procedure)
- **96368** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); **concurrent infusion** (List separately in addition to code for primary procedure)

Therapeutic, Prophylactic, and Diagnostic Injections

- **96374** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); **intravenous push, single or initial substance/drug**
- **96375** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); **each additional sequential intravenous push of a new substance/drug** (List separately in addition to code for primary procedure)

Therapeutic, Prophylactic, and Diagnostic Injections

- **+96376** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each **additional sequential intravenous push of the same substance/drug provided in a facility** (List separately in addition to code for primary procedure)

Therapeutic, Prophylactic, and Diagnostic Injections

- 96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); **subcutaneous or intramuscular**
- 96373 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); **intra-arterial**

Chemotherapy

- Chemotherapy administration codes apply to parenteral administration of non- radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers.

Chemotherapeutic Drugs

- **Antineoplastic Drugs** -Typically all J codes that have the first number after the J =9 e.g. J9XXX
- **Monoclonal Antibodies** – Examples -
infliximab, rituximab, alemtuzumb,
gemtuzumab, and trastuzumab
- **Hormonal Antineoplastics** – Examples -
leuprolide acetate and goserelin acetate

Chemotherapy

- 96401- 96402
 - Hormonal or non hormonal
 - See Compliance Drug List
 - 96409 – 96411 Push
 - 96413 - 96417 Infusion

Administration Codes

- 96400 Subcutaneous or intramuscular
- 96408 Intravenous, push technique
- 96410 Intravenous, infusion technique, up to one hour
- +96412 Intravenous, infusion technique, 1-8 hours, each additional hour

Administration

96414 - Intravenous, infusion technique, initiation of prolonged infusion (more than 8 hours) requiring the use of a portable or implantable infusion pump

- No separate charge to disconnect
- Units of service = 1
- May bill 96410 & 96414 on same date of service
 - Different meds – one in office & one in send home pump
- Code pump insertion, revision, removal separately

Hydration 96360-96361

- The hydration codes are used to report a hydration IV infusion which consists of a pre-packaged fluid and /or electrolytes (e.g. normal saline, D5-1/2 normal saline +30 mg EqKC1/liter) but are not used to report infusion of drugs or other substances

Hydration

- Usually Infused at 125cc/hr to “wide open” for rehydration
 - Lesser rates for hydration need to be explained in the documentation.
- Having the diagnosis on the claim as dehydration alone is not sufficient
- Citing, “Will hydrate patient” is not sufficient
- Must document clinical need for hydration

Hydration

- In some cases the drug is toxic to the kidneys and the saline solution is required to accompany the therapy
- In the case where chemotherapy requires hydration there is often a second line
 - This is because it would be equally as hazardous to run the chemotherapy drug in at a high rate of infusion.

Time

- Infusions of 15 minutes or less are codes as an IV Push (IVP)
- There must be at least 31 minutes to count the first hour
- There must be at least 91 minutes to count a second hour

Infusion Time

- Rounding

- After the first hour, service times are rounded up and down to the nearest hour.
 - One hour and 29 minutes becomes one hour
 - One hour and 31 minutes becomes two hours

Infusion In ED

- Make certain nurses note transfer time and how much was administered.
- Make certain you only have one initial infusion per encounter.
 - If patient goes to observation from ED still same encounter, only one initial IV service.
 - Per CMS (CR7271), Transmittal 2141

CMS on Time

- The physician may report the infusion code for “each additional hour” only if the infusion interval is greater than 30 minutes beyond the 1 hour increment. For example if the patient receives an infusion of a single drug that lasts 1 hour and 45 minutes, the physician would report the “initial” code up to 1 hour and the add-on code for the additional 45 minutes.

Implantable Pumps

- **Medicare**

- Pump used to administer a drug that is included as an indicated use on the pump's FDA-approved labeling, and
- The drug is reasonable and necessary for the treatment of an individual patient; and
- It is medically necessary that the drug be administered by an implanted infusion pump.

Implantable Pump

CPT Assistant, Fall 1995:

“The implantable infusion pump is a device with a build-in reservoir that contains medication within the implanted system.”

“Medication is administered systematically, through the attached catheter that is inserted into a central vein.”

Take Home Pump

- Not eligible for separate reimbursement by a physician
- Considered included in the chemotherapy administration code
- Additional reimbursement only if billed by a DME vendor

Shunt Tubing

61070 Puncture of shunt tubing or reservoir for aspiration or injection procedure

- Includes aspiration of Ommaya reservoir to obtain CSF sample for cytology and culture

Subcutaneous Reservoir

61215 Insertion of subcutaneous
reservoir, pump or continuous
infusion system for connection to
ventricular catheter

Subcutaneous Reservoir

+61517 Implantation of brain
intracavitary chemotherapy agent

- Only billed in conjunction with 61510 or 61518
- Implantation of BCNU wafers or local application of cytostatic drugs in the resected tumor bed.
- Not reported for brachytherapy insertion.

Intrathecal Pump

62350 Implantation, revision or repositioning of tunneled Intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir-infusion pump; without laminectomy

Intrathecal Pump

**62360 Implantation or replacement of device
for Intrathecal or epidural drug infusion;
subcutaneous reservoir**

**62361 Implantation or replacement of device
for Intrathecal or epidural drug infusion;
non-programmable pump**

Intrathecal Pump

62362 Implantation or replacement of device for Intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming

Intrathecal Pump

62367 Electronic analysis of programmable, implanted pump for Intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming

- Direct physician supervision

62368 ... with reprogramming

- Direct physician supervision

STOP and NOTE!

- Do not code 62367-62370 with 95990 or 95991!
- Use 95990 or 95991 when
 - Refill and Maintenance a reservoir or implantable infusion pump for spinal and brain drug.
 - **there is no reprogramming**

Units of Service

- Line up infusions by time
 - First infusion 1200 – 135 (1 time unit Unit)
 - 2nd infusion New drug 140 – 340 (2 time units)
 - IVP of drug 1 PM
 - IVP of same drug 315 PM

Codes

Therapeutic

- 96365
- 96366
- 96367
- 96375
- 96376

Chemotherapy

- 96413
- 95415
- 96417
- 96411
- 96376

Reconciling Charges

- Charge capture of supplies (Huber Needles and Lowsorb tubing)
- Drugs coded should match orders
 - NDC codes usually requested from pharmacy
- Infusions
- Time
 - Remember infusion time is nursing time
 - Time starts with infusion not IV placement
- Other separately codeable services e.g. care for untoward drug reaction.

Medication Units

- Must have dose to drive units
- 2ml is not a dose
- 40mg/1ml of Diazepam = 8 units of J3360
 - If you give 1 ml
 - What if you give 0.5 ml ?
 - What if you give 1.5 ml ?

Medication Dose

- Mg versus Mcg
- Meq
- IU
- mCi
- Units
- Per Vial
- Multidose Vial and Wastage

Infusions & 99211

Medicare Carriers Manual,

- For services furnished on or after January 1, 2004, do not allow payment for CPT code 99211, with or without modifier 25, if it is billed with a chemotherapy drug infusion code or a chemotherapy administration code.
- Apply this policy to code 99211 when it is billed with a diagnostic or therapeutic injection code on or after January 1, 2005.

Unbundling Alert

- **Do not assign the following codes with intravenous infusions when performed in same encounter:**
 - **36000 (needle introduction)**
 - **36410**
 - **36415**
 - **96591**
 - **96592**

Documentation

- **Pump status before and after refill**
- **Patient' s response to current medication dose and rate**
- **Reasons for any change in dose or type of medication**
- **New MD orders should support any and all changes**

96406 Note

- When billed in conjunction with other codes for injection, excision, destruction, debridement, or shaving of lesions, excision of skin tags or repair of wounds or wound dehiscence will be denied as not separately payable.
- Performed by the physician
- No separate charge for the drugs

Physician Orders

- Required Documentation
 - Prescription date
 - Patient name, medical record number
 - Protocol code (if used), or regimen as applicable
 - Name of drug
 - Approved generic or brand names, no abbreviations
 - Daily dose & number of days of treatment
 - Route of administration & instructions
 - Starting dates (& times, if appropriate)
 - Start times, stop times, other pertinent information

Staff Documentation

- IV Site, Type, Patency, Flush, Dressings
- Drug – Dose
- Infusate – Type and Amount
- IV To Keep Open
- Infusion Start Time
- Infusion Stop Time
- Patient Reaction
- Pertinent lab work

Documentation

- **Any necessary reassessment of the patient's overall condition and treatment goals**
- **Proof that all application “incident to” requirements are met**
- **Proof that any medication billed represents a cost to the physician or group requesting payment**

Unlisted Procedure

- | Detailed description of the procedure performed
- | Copies of articles in medical journals – clinical trials, medical indications
- | Patient diagnosis, CC, presenting signs and symptoms
- | Any concurrent problems requiring treatment or management

Drug Administration and Federal Guidelines

CMS Transmittal 2368

- Pharmacy Billing for Drugs Provided “Incident To” a Physician Service
 - Implemented January 1 2013
 - No more Brown Bagging meds
 - Medicare Part B can no longer be billed for medications dispensed directly to the patient for administration “incident to” a physician service.
 - If you fill the pump you supply the drug.
 - No send patients to the outpatient pharmacy
 - <http://www.cms.gov/transmittals/downloads/R2368CP.pdf>

Self Administered Drugs

SADs

- Administered by the patient to him or herself.
- This does NOT include administration by spouses, nursing aides, allied health professionals, or physicians.
- Oral medications are considered self administered drugs.
- Payment for an oral drug is made as a rare exception when the drug is an oral anti cancer drug or an oral antiemetic that is given with chemotherapy treatments
- (See IOM 100-02, Chapter 15, Section 50.5.3 and 50.5.4).

Administered

- The term “administered” refers only to the physical process by which the drug enters the patient’s body.
 - Only **injectable** (including intravenous) drugs are eligible for **inclusion** under the “incident to” benefit.
 - Other routes of administration considered to be usually **self-administered** by the patient, include but are not limited to,
 - oral drugs,
 - suppositories,
 - topical medications

Usually

- For the purposes of applying this exclusion, the term “usually” means more than 50 percent of the time for all Medicare beneficiaries who use the drug.

SAD and Route

- Carriers are told to Assume
 - IV not usually SAD
 - IM not usually SAD
 - SQ depends on frequency and acute versus chronic
 - **Acute Condition** - Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition were longer term, it would be more likely that the patient would self-administer the drug.
 - **Frequency of Administration** - How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient

Approved Use of the Drug

- Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. (See the Medicare Benefit Policy Manual, Chapter 16, “General Exclusions from Coverage,” §20.) Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA approved drug or biological, if:
 - It was injected on or after the date of the FDA’s approval;
 - It is reasonable and necessary for the individual patient; and
 - All other applicable coverage requirements are met.

Unlabeled Drug Use

- An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA.
- FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.
- In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in §50.5.

Medical Necessity

- **Not for Particular Illness**

- Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations).
- Charges for medications, e.g., vitamins, given simply for the general good and welfare of the patient and not as accepted therapies for a particular illness are excluded from coverage.

Medical Necessity

- **Injection Method Not Indicated**
 - Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration.

Medical Necessity

- **Excessive Medications**
 - Medications administered for treatment of a disease which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered.

Off Label Use of Drugs

- Effective January 1, 1994, off-label, medically accepted indications of Food and Drug Administration-(FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are identified under the following conditions:
 - indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or,
 - narrative text in AHFS-DI or Clinical Pharmacology is supportive.

Chemotherapy Regime

- A regimen is a combination of anti-cancer agents clinically recognized for the treatment of a specific type of cancer.
- Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature.

Less Than Effective Drug

- This is a drug that has been determined by the Food and Drug Administration (FDA) to lack substantial evidence of effectiveness for all labeled indications. Also, a drug that has been the subject of a Notice of an Opportunity for a Hearing (NOOH) published in the “Federal Register” before being withdrawn from the market, and for which the Secretary has not determined there is a compelling justification for its medical need, is considered less than effective. This includes any other drug product that is identical, similar, or related. Payment may not be made for a less than effective drug.

Immunosuppressive Drugs

- For patients receiving post transplant immunosuppressive drugs after 2000 there is no time limit for coverage if FDA approved.
- May cover some FDA approved drugs for nonlabeled use
- Includes some prescription meds such as Prednisone that are used in conjunction with immunosuppressive drugs

Approved Immunosuppressives

- Sandimmune (cyclosporine), Sandoz Pharmaceutical;
- Imuran (azathioprine), Burroughs Wellcome;
- Atgam (antithymocyte globulin), Upjohn;
- Orthoclone OKT3 (Muromonab-CD3), Ortho Pharmaceutical;
- Prograf (tacrolimus), Fujisawa USA, Inc.;
- Celicept (mycophenolate mofetil, Roche Laboratories;
- Daclizumab (Zenapax);
- Cyclophosphamide (Cytosan);
- Prednisone; and
- Prednisolone.

Erythropoietin (EPO)

- The statute provides that EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis.
- Coverage is available regardless of whether the drug is administered by the patient or the patient's caregiver.
- EPO is a biologically engineered protein which stimulates the bone marrow to make new red blood cells.

Erythropoietin (EPO)

- **NOTE:** Non-ESRD patients who are receiving EPO to treat anemia induced by other conditions such as chemotherapy or the drug zidovudine (commonly called AZT) must meet the coverage requirements in §50.

EPO

- EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis when:
 - It is administered in the renal dialysis facility; or
 - It is self-administered in the home by any dialysis patient (or patient caregiver) who is determined competent to use the drug and meets the other conditions detailed in the OLM

EPO Documentation

- It is expected that the ESRD facility or hospital outpatient department will maintain the following information in each patient's medical record to permit the review of the medical necessity of EPO.
 1. Diagnostic coding;
 2. Most recent creatinine prior to initiation of EPO therapy;
 3. Date of most recent creatinine prior to initiation of EPO therapy;
 4. Most recent hematocrit (HCT) prior to initiation of EPO therapy;
 5. Date of most recent hematocrit (HCT) prior to initiation of EPO therapy;
 6. Dosage in units/kg;
 7. Weight in kgs; and
 8. Number of units administered.

EPO Coverage

- **Preselection Monitoring**
 - The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

EPO Coverage

- **2 Conditions the Patient Must Meet**
 - The assessment must find that the patient meets the following conditions:
 - a. Is a dialysis patient;

EPO Coverage

- b. Has a hematocrit (or comparable hemoglobin level) that is as follows:
 - For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent.
 - Patients with severe angina, severe pulmonary distress, or severe hypotension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.
- For a patient who has been receiving EPO from the facility or the physician, between 30 and 36 percent.

EPO Coverage

c. Is under the care of:

- A physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and
- A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

Documentation for EPO

- The following information in each patient's medical record to permit the review of the medical necessity of EPO.
 - Diagnostic coding;
 - Most recent creatinine prior to initiation of EPO therapy;
 - Date of most recent creatinine prior to initiation of EPO therapy;
 - Most recent hematocrit (HCT) prior to initiation of EPO therapy;
 - Date of most recent hematocrit (HCT) prior to initiation of EPO therapy;
 - Dosage in units/kg;
 - Weight in kgs;
 - Number of units administered.

Q Codes for EPO

- Q4081 Injection Epotin Alfa **100 units** (for ESRD on Dialysis) Epogen or Procrit
- J0885 Injection Epotin Alfa **1000 units** (for **non- ESRD** use) Epogen or Procrit
- J0886 Injection Epotin Alfa **1000 units** (for **ESRD on Dialysis**) Epogen or Procrit

Reasonable and Necessary ESA Use

- CMS has determined that ESA treatment for the anemia secondary to a regimen of myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia is reasonable and necessary only under the following specified conditions:
- The hemoglobin level immediately prior to the first administration is < 10 g/dL (or the hematocrit is $< 30\%$) and the hemoglobin level prior to any maintenance administration is < 10 g/dL (or the hematocrit is $< 30\%$.);
- The starting dose for ESA treatment is up to either of the recommended Food and Drug Administration (FDA) approved label starting doses for cancer patients receiving chemotherapy, which includes the, 150 U/kg/3 times weekly or the 40,000 U weekly doses for epoetin alfa and the 2.25 mcg/kg/weekly or the 500 mcg once every three week dose for darbepoetin alpha;

Reasonable and Necessary ESA Use

- Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10 g/dL (or hematocrit is $< 30\%$) 4 weeks after initiation of therapy and the rise in hemoglobin is ≥ 1 g/dL (hematocrit $\geq 3\%$);
- • For patients whose hemoglobin rises < 1 g/dl (hematocrit rise $< 3\%$) compared to pretreatment baseline over 4 weeks of treatment and whose hemoglobin level remains < 10 g/dL after 4 weeks of treatment (or the hematocrit is $< 30\%$), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the hemoglobin rises < 1 g/dl (hematocrit rise $< 3\%$) compared to pretreatment baseline by 8 weeks of treatment;

Reasonable and Necessary ESA Use

- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in hemoglobin > 1 g/dl (hematocrit $> 3\%$) over any 2 week period of treatment unless the hemoglobin remains below or subsequently falls to < 10 g/dL (or the hematocrit is $< 30\%$). Continuation and reinstitution of ESA therapy must include a dose reduction of 25% from the previously administered dose; and
- • ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

Not Reasonable and Necessary ESA Use

Either because of a deleterious effect of ESAs on the underlying disease, or because the underlying disease increases the risk of adverse effects related to ESA use, CMS has also determined that ESA treatment is not reasonable and necessary for beneficiaries with the following clinical conditions:

Not Reasonable and Necessary ESA Use

- Any anemia in cancer or cancer treatment patients due to folate deficiency (diagnosis code 281.2), B-12 deficiency (281.1 or 281.3), iron deficiency (280.0-280.9), hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9, 283.10, 283.19), bleeding (280.0 or 285.1), or bone marrow fibrosis;
- Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91), or erythroid cancers (207.00-207.81);

Not Reasonable and Necessary ESA Use

- Anemia of cancer not related to cancer treatment;
- Any anemia associated only with radiotherapy;
- Prophylactic use to prevent chemotherapy-induced anemia;
 - Prophylactic use to reduce tumor hypoxia;
 - Erythropoietin-type resistance due to neutralizing antibodies; and
 - Anemia due to cancer treatment if patients have uncontrolled hypertension.
- <http://www.cms.gov/MLN MattersArticles/downloads/MM5818.pdf>

HCPCS Modifiers for EPO

- **EA** - Erythropoietic Stimulating Agent (ESA)
Administered To Treat Anemia Due To Anti-Cancer Chemotherapy
- **EB** - Erythropoietic Stimulating Agent (ESA)
Administered To Treat Anemia Due To Anti-Cancer Radiotherapy
- **EC** Erythropoietic Stimulating Agent (ESA)
Administered To Treat Anemia Not Due To Anti-Cancer Radiotherapy Or Anti-Cancer Chemotherapy

HCPCS Modifiers for EPO

- **ED** - Hematocrit Level Has Exceeded 39% (Or Hemoglobin Level Has Exceeded 13.0 G/Dl) For 3 Or More Consecutive Billing Cycles Immediately Prior To And Including The Current Cycle
- **EE** - Hematocrit Level Has Not Exceeded 39% (Or Hemoglobin Level Has Not Exceeded 13.0 G/Dl) For 3 Or More Consecutive Billing Cycles Immediately Prior To And Including The Current Cycle
- **EJ** - Subsequent claims for a defined course of therapy, e.g., epo, sodium hyaluronate, infliximab

Modifier EC

- *Effective for claims with dates of service on and after January 1, 2008, non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) shall be denied when any one of the following diagnosis codes is present on the claim:*
 - *any anemia in cancer or cancer treatment patients due to folate deficiency (281.2),*
 - *B-12 deficiency (281.1, 281.3),*
 - *iron deficiency (280.0-280.9),*

Modifier EC

- *Effective for claims with dates of service on and after January 1, 2008, non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) shall be denied when any one of the following diagnosis codes is present on the claim:*
 - *hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9-283.10, 283.19), or*
 - *bleeding (280.0, 285.1),*
 - *anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91); or*
 - *erythroid cancers (207.00-207.81).*

Oral Anti Cancer Drugs

- Be prescribed by a physician or other practitioner licensed under State law to prescribe such drugs as anti-cancer chemotherapeutic agents;
- Be a drug or biological that has been approved by the Food and Drug Administration (FDA);
- Have the same active ingredients as a non-self-administrable anti-cancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anti-cancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's

Oral Anti Cancer Drugs

- “Approved Drug Products” (Orange Book), “Physician’s Desk Reference” (PDR), or an authoritative drug compendium;
- Be used for the same indications, including unlabeled uses, as the non-self-administrable version of the drug; and
- Be reasonable and necessary for the individual patient.

Approved Oral Cancer Drugs

- Busulfan 2 mg J8510
- Capecitabine 150 mg J8520
- Capecitabine 500 mg J8521
- Methotrexate 2.5 mg J8610
- Cyclophosphamide 25 mg J8530
- Etoposide 50 mg J8560
- Melphalen 2 mg J8600

Oral Anti-Nausea (Anti-Emetic) Drugs

- Effective January 1, 1998, Medicare also covers self-administered anti-emetics, which are necessary for the administration and absorption of the anti-neoplastic
- Section 1861(s)(2) of the Act extends coverage to oral anti-emetic drugs that are used as full replacement for intravenous dosage forms of a cancer regimen under the following conditions: see next slide

Oral Anti-Nausea (Anti-Emetic) Drugs

- Coverage is provided only for oral drugs approved by the Food and Drug Administration (FDA) for use as anti-emetics;
- The oral anti-emetic must either be administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen;
- Oral anti-emetic drugs administered with a particular chemotherapy treatment must be initiated within two hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed 48 hours from that time;

Oral Anti-Nausea (Anti-Emetic) Drugs

- The oral anti-emetic drugs provided must be used as a full therapeutic replacement for the intravenous anti-emetic drugs that would have otherwise been administered at the time of the chemotherapy treatment.
- Only drugs pursuant to a physician's order at the time of the chemotherapy treatment qualify for this benefit. The dispensed number of dosage units may not exceed a loading dose administered within two hours of the treatment, plus a supply of additional dosage units not to exceed 48 hours of therapy.

Approved Antiemetics

- Q0180 Dolasetron mesylate, 100 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24 hour dosage regimen
- Q0181 Unspecified oral dosage form, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for a IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen

Approved Antiemetics

- Q0163 Diphenhydramine hydrochloride, 50 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at time of chemotherapy treatment not to exceed a 48 hour dosage regimen
- Q0164 Prochlorperazine maleate, 5 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0165 Prochlorperazine maleate, 10 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0166 Granisetron hydrochloride, 1 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24 hour dosage regimen

Approved Antiemetics

- Q0167 Dronabinol, 2.5 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0168 Dronabinol, 5 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0169 Promethazine hydrochloride, 12.5 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen

Approved Antiemetics

- Q0170 Promethazine hydrochloride, 25 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0171 Chlorpromazine hydrochloride, 10 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0172 Chlorpromazine hydrochloride, 25 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0173 Trimethobenzamide hydrochloride, 250 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen

Approved Antiemetics

- Q0174 Trimethobenzamide hydrochloride, 250 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0175 Perphenazine, 4 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0176 Perphenazine, 8mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0177 Hydroxyzine pamoate, 25 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen

Approved Antiemetics

- Q0178 Hydroxyzine pamoate, 50 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0179 Ondansetron hydrochloride 8 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
- Q0810 Dolasteron mesylate , 100mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 24-hour dosage regimen.

Facility vs. Professional

- UB02
 - Code hierarchy based on CPT directions
Chemo, Therapeutic, Hydration
 - Rev Codes
 - CPT Codes
 - ICD 9CM Codes
 - Pharmacy Bills drugs
- CMS 1500
 - Code based on reason for visit
 - CPT codes
 - ICD9 CM Codes
 - Can only code drugs if physician buys them from the pharmacy
 - Incident to in the office

Thank YOU for Attending!

