



**CALIFORNIA HEALTH ADVOCATES**  
Medicare: Policy, Advocacy and Education



# **MEDICARE DRUG COVERAGE OR NAVIGATING THE MAZE OF MEDICARE PARTS A-B-C-D**

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# OBJECTIVES

- Understand how drugs and biologicals are covered by Parts A, B, C and D of Medicare.
- Understand the basic criteria for certain self-administered drugs to be covered by Part B.
- Be able to determine when a drug should be covered by Part B vs. Part D.
- Understand that drug coverage has evolved in Medicare over the last 35 years.





**July 30, 1965**



# MEDICARE COVERAGE

- Law Implemented by Congress
  - Medicare is Title XVIII of the Social Security Act
  - Passed as H.R. 6675 by the 89<sup>th</sup> Congress
- Federal Regulations issued by the Department
  - C.F.R. Part 42 Chapter 400ff regulates Medicare
- Manual Instructions for details on Coverage Interpretation and Claim Processing Instructions
  - CMS has over 25 manuals of instructions



# MEDICARE PRESCRIPTION DRUG COVERAGE

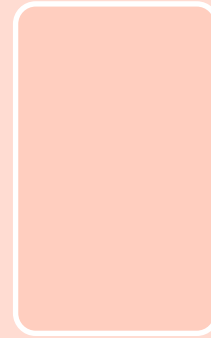
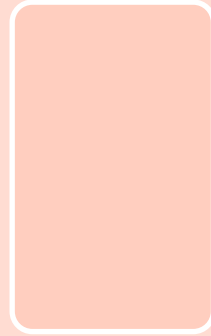
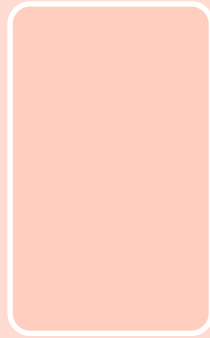
- Prescription drug coverage under Part A, B, C or D depends on
  - Medical necessity
  - Health care setting
  - Medical indication
  - Any special drug coverage requirements



# THE PARTS OF MEDICARE



Part A  
Hospital  
Insurance



# PART A PRESCRIPTION DRUG COVERAGE

## **Inpatient Hospital or Critical Access Hospital**

- Medicare pays for drugs and biologicals as inpatient hospital or inpatient CAH services only if—
  - (1) They represent a cost to the hospital or CAH;
  - (2) They are ordinarily furnished by the hospital or CAH for the care and treatment of inpatients; and
  - (3) They are furnished to an inpatient for use in the hospital or CAH.

Ref: 42 CFR 409.13





# PAR A PRESCRIPTION DRUG COVERAGE

## **Post hospital Skilled Nursing Facility (SNF) Care**

- Medicare pays for drugs and biologicals as post-hospital SNF care only if—
  - (1) They represent a cost to the facility;
  - (2) They are ordinarily furnished by the facility for the care and treatment of inpatients; and
  - (3) They are furnished to an inpatient for use in the facility.

Ref: 42 CFR 409.25



# PART A PRESCRIPTION DRUG COVERAGE

## Hospice Care

- Drugs are only covered if they are:
  - Drugs as defined in section 1861(t) of the Act, and
  - Used primarily for the *relief of pain and symptom control* related to the individual's terminal illness
  
- Ref: 42 CFR 202



# PART A PRESCRIPTION DRUG COVERAGE

## Home Health Services (HHA) Under Part A

- ❖ Drugs and biologicals are excluded from payment under the Medicare home health benefit.
- A **drug** is any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other condition or for the relief of pain or suffering or to control or improve any physiological pathologic condition.
- A **biological** is any medicinal preparation made from living organisms and their products including, but not limited to, serums, vaccines, antigens, and antitoxins.



## QUIZ

Max has Original Medicare and a Part D plan. He recently got prescription drugs during a Medicare-covered stay at a skilled nursing facility (SNF).

1. Will Medicare pay for his prescription drugs?

Yes

No

2. If yes, which part of Medicare will cover them?

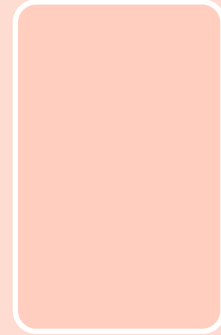
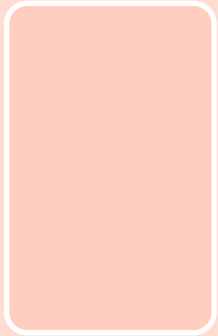
Part A

Part B

Part D



# THE PARTS OF MEDICARE



**Part B  
Medical  
Insurance**

# PART B PRESCRIPTION DRUG COVERAGE

- Medicare provides limited benefits for outpatient drugs (Part B coverage).
- Program covers drugs furnished “incident to” a physician’s service provided drugs are
  - Usually not self-administered (pill form or self-injection), and
  - Meet certain requirements
- Incident to a physician’s professional services means the services or supplies (including drugs) are furnished as an integral part of the service in the course of diagnosis or treatment of an injury or illness.
  - To be covered, the supplies must be an expense to the physician or legal entity billing for the supply.



## PART B PRESCRIPTION DRUG COVERAGE

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of a drug or biological;
- They are of the type not usually self-administered;
- They meet all of the general requirements for coverage of items as incident to a physician's service;



# PART B PRESCRIPTION DRUG COVERAGE

Requirements continued:

- They are reasonable and necessary for the diagnosis or treatment of the illness or injury;
- They are not excluded as non-covered immunizations; and
- They have not been determined by the FDA to be less than effective.





# PART B PRESCRIPTION DRUG COVERAGE

Exceptions to the exclusion of self-administered drugs, provided by statute:

- Blood-clotting factors
- Drugs used in immunosuppressive therapy
- Erythropoietin (EPO) for dialysis patients
- Osteoporosis drugs for certain homebound patients
- Certain oral anti-cancer drugs
- Oral anti-emetics (anti-nausea) used in certain situations
- Intravenous Immune Globulin for Primary Immune Deficiency Disease, provided in the home
- Drugs for the effective use of Durable Medical Equipment



# PART B – HEMOPHILIA CLOTTING FACTORS

Effective July 18, 1984, Section 1861 (s)(2)(1) of the Act provides Medicare coverage of blood clotting factors for hemophilia patients competent to use such factors to control bleeding

- Without medical supervision
- Has specific diagnosis
- Patient deemed competent to use such factors without medical supervision



## PART B – IMMUNOSUPPRESSIVE DRUGS

- Until January 1, 1995, immunosuppressive drugs were covered under Part B for one year only (365 days), following the discharge from a hospital for a Medicare covered organ procedure
- With the passage of the Balanced Budget Act of 1997, there was an increase of time for coverage from 18 months to eventually 36 months
- Effective for immunosuppressive drugs furnished on or after December 21, 2000, Medicare Part B will cover the drugs as long the beneficiary continues entitlement to Medicare Part B and there was a Medicare covered transplant on record



# PART B—COVERED IMMUNOSUPPRESSIVE DRUGS\*

- Azathioprine-oral
- Azathioprine-parenteral
- Cyclophosphamide-oral
- Cyclosporine-oral
- Cyclosporine-parenteral
- Daclizumab-parenteral
- Lymphocyte Immune Globulin, Antithymocyte Globulin-parenteral
- Methotrexate-oral
- Methylprednisolone-oral
- Methylprednisolone Sodium Succinate Injection
- Muromonab-Cd3-parenteral
- Mycophenolate Acid-oral
- Mycophenolate Mofetil-oral
- Prednisolone-oral
- Prednisone-oral
- Sirolimus-oral
- Tacrolimus-oral
- Tacrolimus-parenteral

\*List is subject to change. From the May 2014 CMS Training slide.



## PART B - ERYTHROPOIETIN (EPO) FOR DIALYSIS PATIENTS

- Statute provides that EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis.
- Coverage applies whether the drug is administered by the patient or the patient's caregiver.
  - It is covered when administered in the renal dialysis facility, or
  - Self-administered in the home, if the patient (or caregiver) is determined to be competent to administer the drug
- EPO is a biologically engineered protein which stimulates the bone marrow to make new red blood cells.
- Possible limited coverage for a non-ESRD patient to treat anemia induced by other conditions such as chemotherapy



## PART B – OSTEOPOROSIS DRUGS FOR CERTAIN HOMEBOUND PATIENTS

- Sections 1861 (m) and 1861 (kk) of the Social Security Act provides for coverage of FDA approved injectable drugs for the treatment of osteoporosis.
- This was provided in the Omnibus Budget Reconciliation Act of 1990 that was signed into law on November 5, 1990.
- Drug is provided by an HHA to a female beneficiary who is currently receiving services under an open HH plan of care, meets criteria for HHA benefits and meet 3 conditions.



# PART B – OSTEOPOROSIS DRUGS FOR CERTAIN HOMEBOUND PATIENTS

## **Conditions for coverage of drug:**

- Beneficiary is eligible for Medicare Part B coverage of HH services;
- Has sustained a bone fracture certified by a physician that is related to post-menopausal osteoporosis; and,
- The beneficiary's physician certifies she is unable to learn the skills to self-administer the drug, or is otherwise physically or mentally incapable of administering the drug, and her family or caregivers are unable/unwilling to administer the drug.

Drug is paid under Part B; Nursing visit may be Part A or B. Ref: Medicare Benefit Policy Manual, Chp. 7.



## PART B – ORAL ANTI-CANCER DRUGS

Effective January 1, 1994, Part B covers oral anti-cancer drugs. Criteria for coverage includes:

- Drug is reasonable and necessary for patient;
- Drug is prescribed by a physician or other licensed practitioner;
- Be a drug or biological approved by the FDA;
- Drug has the same active ingredient as a non-self-administered chemotherapeutic drug or biological that is covered when furnished incident to a physician's service; and
- Drug must be used for same indications, including unlabeled uses, as the non-self-administered version of the drug.





# PART B— COVERED ORAL ANTICANCER DRUGS\*

- Busulfan
- Capecitabine
- Cyclophosphamide
- Etoposide
- Fludarabine phosphate
- Melphalan
- Methotrexate
- Temozolomide
- Topotecan

\*List is subject to change.

List from Noridian website for Local Coverage Determination  
L11574 .



## PART B - ORAL ANTI-EMETICS (ANTI-NAUSEA)

- Effective January 1, 1998, Section 1861 (s) (2) of the Social Security Act extended coverage to oral anti-emetic drugs used as full replacement for IV dosages of a cancer regimen if:
  1. Coverage is provided only for oral drugs approved by FDA for use as anti-emetics;
  2. It must be administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen;



## PART B - ORAL ANTI-EMETICS (ANTI-NAUSEA)

3. If administered with a particular chemotherapy treatment, it 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.

4. It 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.



## PART B - ORAL ANTI-EMETICS (ANTI-NAUSEA)

- Only drugs pursuant to a physician's order at the time of chemotherapy qualify.
- Oral drugs not approved by the FDA for use as an anti-emetic are not covered by this benefit and not reimbursable by this benefit.
- Intravenous anti-emetics may be covered (if medically necessary) if patient fails on oral therapy.
- More than one oral anti-emetic drug may be prescribed and may be covered for concurrent use if needed to fully replace the IV drugs that otherwise would be given.



## PART B—COVERED ORAL ANTIEMETICS

### FOR USE WITHIN 48 HOURS OF CHEMOTHERAPY\*

- 3 oral drug combination of
  - Aprepitant
  - A 5-HT<sub>3</sub> Antagonist
  - Dexamethasone
- Chlorpromazine Hydrochloride
- Diphenhydramine Hydrochloride
- Dolasetron Mesylate (within 24 hours)
- Dronabinol
- Granisetron Hydrochloride
- Hydroxyzine Pamoate
- Ondansetron Hydrochloride
- Nabilone
- Perphenazine
- Prochlorperazine Maleate
- Promethazine Hydrochloride
- Trimethobenzamide Hydrochloride

\*List is subject to change. List from CMS May 2014 Training slide.



## PART B - INTRAVENOUS IMMUNE GLOBULIN (IVIG) FOR PRIMARY IMMUNE DEFICIENCY DISEASE, PROVIDED IN THE HOME

- Effective for dates of service on or after January 1, 2004, law provided for coverage of IVIG for the treatment of primary immune deficiency diseases in the home.

It is covered when:

- Patient has diagnosed primary immune deficiency disease;
- It is administered in the patient's home; and
- Physician determines that administration in the home is medically appropriate.
- ❖ For coverage, does not need to be administered through a piece of DME.



# PART B - DRUGS FOR THE EFFECTIVE USE OF DURABLE MEDICAL EQUIPMENT

- Payment may be made for supplies that are necessary for the effective use of DME.
- Supplies include drugs and biologicals.
  - They must be put directly into the DME to achieve the therapeutic benefit of the DME or
  - To assure proper functioning of the DME.
- Must be determined that drug or biological is reasonable and necessary for the treatment of the illness or injury or to improve the functioning of a malformed body member.
- Coverage is not as a drug, but as a supply for the covered DME item.



# PART B - DRUGS FOR THE EFFECTIVE USE OF DURABLE MEDICAL EQUIPMENT

Requirements include

- Entity that dispenses the drug must furnish it directly to the patient for whom the prescription is written.
- Entity that dispenses must
  - Have a Medicare supplier number
  - Must possess a current license to dispense drugs in State
  - Must bill and receive payment in its own name.

Ref: Medicare Benefit Policy Manual, Chp. 15 and  
Noridian Local Medical Policy L11570.





## PART B - IMMUNIZATION COVERAGE

- Part B covers Certain immunizations as part of Medicare-covered preventive services
  - Pneumococcal shot -July 1, 1981
  - Hepatitis B shot – 1984
  - Flu shot – May 1, 1993
- The Part B program also covers vaccines that are necessary to treat an injury or illness
  - Tetanus shot



# PART B EXCLUSION - SELF-ADMINISTERED DRUGS IN HOSPITAL OUTPATIENT SETTINGS

- Part B doesn't cover self-administered drugs in a hospital outpatient setting
  - Unless needed for hospital services
  - This includes when in observation status at hospital
- If enrolled in Part D\*, drugs may be covered
  - If not admitted to hospital
  - May have to pay and submit for reimbursement

\*Will discuss in Part D

Ref: CMS Product No. 11333 (How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings)



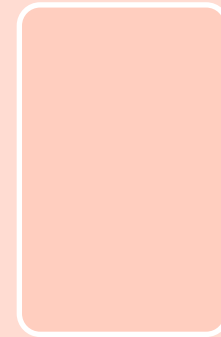
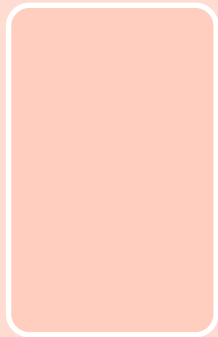
# QUIZ

Which of these vaccines may **NOT** be covered under Medicare Part B?

- a. Flu vaccine
- b. Shingles vaccine
- c. Hepatitis B vaccine
- d. Pneumococcal pneumonia vaccine



# THE PARTS OF MEDICARE



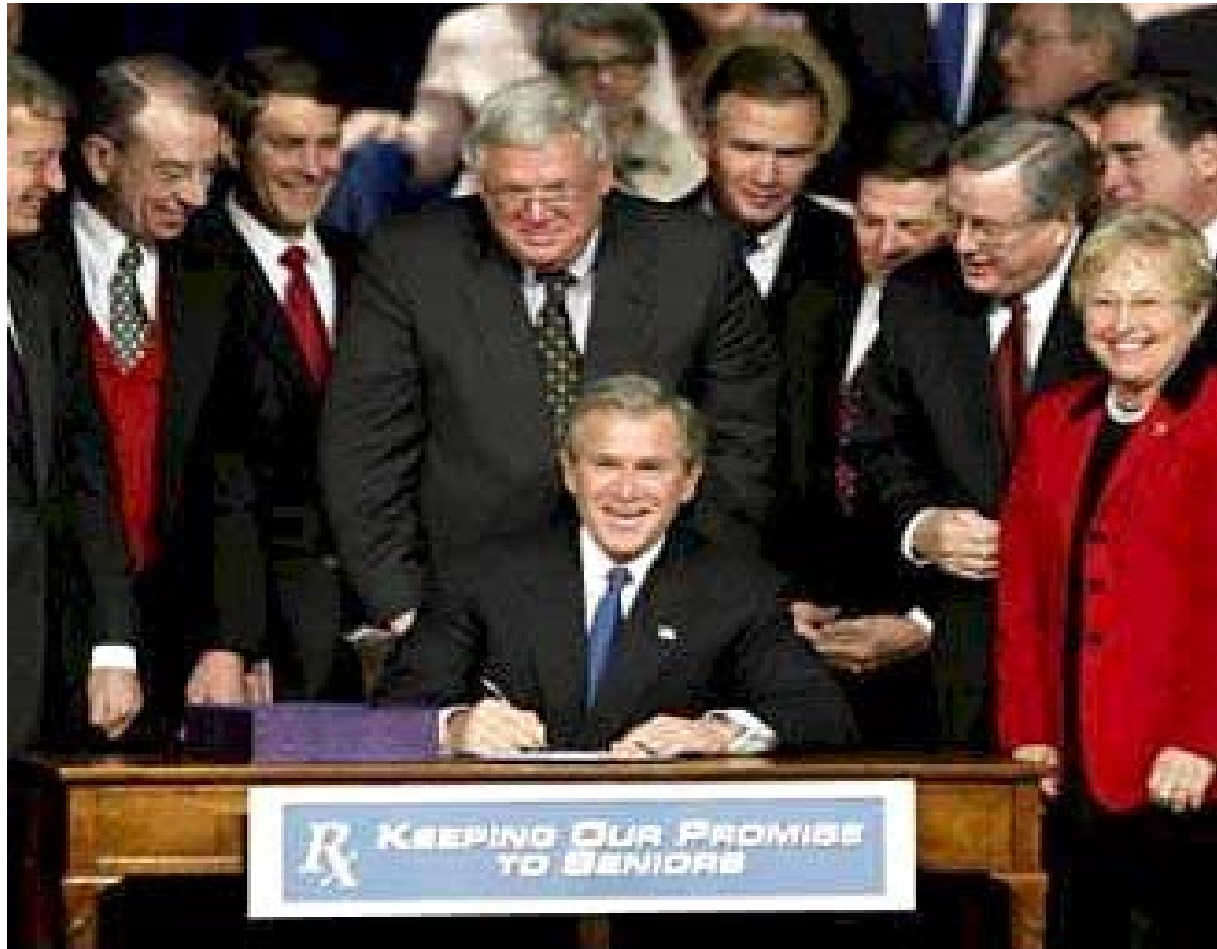
**Part C  
Medicare  
Advantage  
Plans (like  
an  
HMO/PPO)**  
Includes Part  
A, Part B and  
sometimes  
Part D

## PART C – MEDICARE ADVANTAGE PLANS

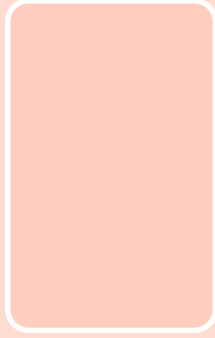
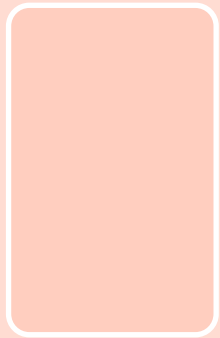
- By law, Medicare Advantage Plans must provide all services covered by Part A and Part B of Original Medicare.
- While the MA Plan may provide more coverage, it cannot provide any less coverage than found in Original Medicare.
- Many MA Plans also provide a Medicare Prescription Plan (Part D).



# December 8, 2003



# THE PARTS OF MEDICARE



Part D  
Medicare  
Prescription  
Drug  
Coverage

# PART D - MEDICARE PRESCRIPTION DRUG COVERAGE

- Prescription drug plans approved by Medicare
- Run by private companies
- Available to everyone with Medicare **A** and/or **B**
- Must be enrolled in a drug plan to get coverage
- Two sources of coverage
  - Medicare Prescription Drug Plans (PDPs)
  - Medicare Advantage Plans with Rx coverage (MA-PDs)





## PART D - MEDICARE DRUG PLANS

- Can be flexible in benefit design
- Must offer at least a standard level of coverage
- May offer different or enhanced benefits
  - Lower deductible
  - Different tier and/or copayment levels
  - Coverage for drugs not typically covered by Part D
- Benefits and costs may change each year
- Formularies will be different among Medicare Drug Plans



## PART D-COVERED DRUGS

- Prescription brand-name and generic drugs
  - Approved by Food and Drug Administration (FDA)
  - Used and sold in United States
  - Used for medically-accepted indications
  - Not covered by Medicare Part A or Part B
- Includes drugs, biological products, and insulin
  - Supplies associated with injection of insulin
- Plans must cover range of drugs in each category
- Coverage and rules vary by plan



## PART D - REQUIRED COVERAGE

- All drugs in 6 protected categories
  - Cancer medications
  - HIV/AIDS treatments
  - Antidepressants
  - Antipsychotic medications
  - Anticonvulsive treatments
  - Immunosuppressants
- All commercially-available vaccines
  - Except those covered under Part B (e.g., flu shot)



## PART D - VACCINE COVERAGE

*Why is the flu vaccine covered by Part B and the Shingles vaccine covered by Part D?*

- When the prescription drug law was passed in 2003, it stated that all drugs already covered by Part A or Part B would continue with that coverage.
- The flu, pneumococcal and hepatitis B vaccines were a covered benefit before 2003.
- The shingles vaccine was approved by the FDA in May 2006 and is therefore now covered by Part D of Medicare.



## PART D - DRUGS EXCLUDED BY LAW

- Drugs for anorexia, weight loss, or weight gain
- Erectile dysfunction drugs when used for the treatment of sexual or erectile dysfunction
- Fertility drugs
- Drugs for cosmetic or lifestyle purposes
- Drugs for symptomatic relief of coughs and colds
- Prescription vitamin and mineral products
- Non-prescription drugs



## PART D - FORMULARY CHANGES

- Plans may change categories and classes
  - Only at beginning of each plan year
  - May make maintenance changes during year
    - e.g., replacing brand-name drug with new generic
- Plan usually must notify you 60 days before changes
  - May be able to use drug until end of calendar year
  - May ask for exception if other drugs don't work
- Plans may remove drugs withdrawn from market without 60-day notification



# Rules Plans Use to Manage Access to Drugs

## Prior Authorization

- Doctor must contact plan for prior approval before drug will be covered
  - Must show medical necessity for drug

## Step Therapy

- Type of prior authorization
- Must first try similar, less expensive drug
- Doctor may request an exception if
  - Similar, less expensive drug didn't work, or
  - Step therapy drug is medically necessary

## Quantity Limits

- Plan may limit drug quantities over a period of time for safety and/or cost
- Doctor may request an exception if additional amount is medically necessary

# THE FOUR PARTS OF MEDICARE



**Part A  
Hospital  
Insurance**



**Part B  
Medical  
Insurance**



**Part C  
Medicare  
Advantage  
Plans (like  
an  
HMO/PPO)  
Includes Part  
A, Part B and  
sometimes  
Part D**



**Part D  
Medicare  
Prescription  
Drug  
Coverage**



# QUIZ

1. If a drug is not covered by Part A or Part B of Medicare, will it be covered by Part D?

- a. Yes
- b. No
- c. It Depends



# QUIZ

2. Which of the following drugs are NOT covered by Medicare Part D?

- a. Insulin
- b. Cancer medications
- c. Barbiturates and benzodiazepines
- d. Prescription vitamin and mineral products



# PART B VS PART D

## **Immunosuppressive Drugs**

- Part B is billed if for a covered Medicare Transplant
- Part D is billed if no covered Medicare Transplant
  - Ex. Transplant occurred before Medicare Entitlement

## **Infusion Supply Drugs**

- Part B is billed if using an infusion pump
  - Drug would need to be listed in the local coverage policy of the Medicare DME MAC
- Part D is billed if using another method (ex. IV drip)
  - If beneficiary is in a hospital or SNF using an infusion pump, coverage for the drug can be covered by Part D, since the beneficiary is not in his/her home



## PART B VS PART D

### **Intravenous immune globulin (IVIg) in the home**

- Part B is billed if the diagnosis is primary immune deficiency disease
- Part D is billed if used for any other diagnosis

### **Certain oral chemotherapy agents which have an infusible version of the drug**

- Part B is billed if related to cancer treatment
- Part D is billed if not related to cancer treatment
  - If drug has no other medically accepted indication besides cancer treatment, should not be on a Part D formulary



## PART B VS PART D

### **Oral anti-emetics used in cancer treatment as a *full replacement for intravenous treatment***

- Part B is billed if related to cancer treatment, is certified by physician it is a full replacement for intravenous administration and is administered within 48 hours of treatment.
- Part D is billed if conditions not met.

### **Hepatitis B vaccine**

- Part B is billed if person is intermediate or high risk.
- Part D is billed if person is not intermediate or high risk.



## PART D AND HOSPICE

- Effective May 1, 2014 CMS is applying prospectively a policy clarification regarding Part D payments for beneficiaries enrolled in Hospice.
- Statute provides that the hospice is responsible for all drugs or biologicals for the palliation and management of the terminal and related conditions.
- As such, drugs covered by the hospice are excluded from Part D coverage.



## PART D AND HOSPICE

### **Drugs Covered under the Hospice Benefit:**

- Hospice plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions.
- Drugs used prior to hospice election but for palliation and management of the terminal illness and related condition, are covered by the hospice benefit if they are part of the plan of care.



# PART D AND HOSPICE

## **Drugs that are a Beneficiary Liability:**

- ❖ Drugs that were for the terminal illness prior to hospice election, may be discontinued if the hospice interdisciplinary group determines it is no longer appropriate and cannot be covered by the hospice benefit.
  - If the beneficiary fills the prescription, it cannot be covered by Part D and the beneficiary is responsible for the cost.
- ❖ Or, the beneficiary requests a drug not on the hospice formulary, and the patient refuses to try a formulary equivalent; or the hospice deems it unreasonable or unnecessary for the terminal/related condition.
  - If the beneficiary fills the prescription, it cannot be covered by Part D and the beneficiary is responsible for the cost.





## PART D AND HOSPICE

### **Drugs covered under Part D when the beneficiary elected Hospice:**

- Drug must be for the treatment of a condition that is completely unrelated to the terminal illness or related conditions.
- It is expected that such drugs will be unusual and in exceptional circumstances.
  - Therefore, drug plans must place a prior authorization on all drugs for beneficiaries who elected hospice to determine if the submitted drug can be covered by Part D.



# RESOURCES

- **CMS Manual on Part B**

- <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf> (especially sections 50-60)

- **CMS Manual on Part D**

- <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf> (especially Appendix C, Attachment 1)

- **CMS Product No. 11315-P (January 2014)**

- **Medicare Drug Coverage under Medicare Part A, Part B, Part C, & Part D**

<http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11315-P.pdf>

- **CMS Product No. 11333 (February 2011)**

- **How Medicare Covers Self-Administered Drugs Given in Hospital Outpatient Settings**

<http://medicare.gov/Pubs/pdf/11333.pdf>





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