

## A Coverage Summary

### Medications/Drugs (Outpatient/Part B)

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<b>Related Medicare Advantage Policy Guidelines:</b>		
<ul style="list-style-type: none"> <li>• <a href="#">Coverage of Drugs and Biologicals for Label and Off-Label Uses</a></li> <li>• <a href="#">Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (NCD 250.5)</a></li> <li>• <a href="#">Dimethyl Sulfoxide (NCD 230.12)</a></li> <li>• <a href="#">Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (NCD 110.21)</a></li> <li>• <a href="#">Erythropoietin Stimulating Agent</a></li> <li>• <a href="#">Halaven (Eribulin Mesylate)</a></li> <li>• <a href="#">Interferon</a></li> <li>• <a href="#">Intravenous Immune Globulin -IVIg</a></li> <li>• <a href="#">Intravenous Immune Globulin-Treatment-Mucocutaneous Blistering Diseases (NCD 250.3)</a></li> <li>• <a href="#">Intravenous Iron Therapy (NCD 110.10)</a></li> <li>• <a href="#">Laetrite and Related Substances (NCD 30.7)</a></li> <li>• <a href="#">L-Dopa (NCD 160.17)</a></li> <li>• <a href="#">Nesiritide for Treatment of Heart Failure Patients (NCD 200.1)</a></li> <li>• <a href="#">Self Administered Drug(s) (SAD)</a></li> <li>• <a href="#">Testosterone Replacement Therapy</a></li> <li>• <a href="#">Thrombolytic Agents</a></li> <li>• <a href="#">Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot (NCD 150.6)</a></li> <li>• <a href="#">Xgeva<sup>®</sup>, Prolia<sup>®</sup> (Denosumab)</a></li> </ul>		

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

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## I. COVERAGE

**Coverage Statement:** Outpatient/Part B medications/drugs are covered when Medicare coverage criteria are met.

**DME Face to Face Requirement:** Effective July 1, 2013, Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including implantable infusion pumps; implantable programmable infusion pump; external ambulatory infusion pump and nebulizers). For DME Face to Face Requirement information, refer to the [Durable Medical Equipment \(DME\), Prosthetics, Corrective Appliances/Orthotics \(Non-Foot Orthotics\) and Medical Supplies Grid](#).

**Guidelines/Notes:**

## 1. **Outpatient Medications/Drug**

### a. **Part B Medications/Drug**

Outpatient (Part B) medications/drugs, in accordance with Medicare coverage criteria, **are covered** when furnished incident to a physician service for drugs that are “not usually self-administered by the patient”. (See Section II for definition of “[not usually administered by patient](#)”)

Coverage is usually limited to drugs or biologicals administered by infusion or injection. However, if the injection is generally self-administered (e.g., Imitrex), it is not covered under Part B. Despite the general limitation on coverage for outpatient drugs under Part B, some self-administered medications/drugs are also covered.

**Refer to [Guideline 3](#) and [Guideline 4](#) below for examples of covered and noncovered medications/drugs.**

*For Medicare’s detailed coverage criteria for medications/drugs under Part B, refer to the [Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals](#). (Accessed October 11, 2016)*

### b. **Part D Medications/Drugs**

A Part D covered drug are available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication. A drug for which coverage is available under Part A or Part B, as it is being “prescribed and dispensed or administered” with respect to the individual, is excluded from the definition of a Part D drug and, therefore, **cannot be included in Part D basic coverage**. CMS interprets this to mean that if payment could be available under Part A or Part B to the individual for such drug, then it will not be covered under Part D.

*Some members may have coverage for Part D drugs under UnitedHealthcare. Refer to the Member’s Pharmacy Booklet or contact the Prescription Solutions Customer Service Department to determine coverage eligibility for Part D prescription drug plan benefit.*

*For Medicare’s detailed coverage information for medications/drugs under Part D, refer to the [Medicare Prescription Drug Benefit Manual, Chapter 6, §10 - Definition of Part D Drugs](#). (Accessed October 11, 2016)*

### c. **Part B vs Part D Medications/Drugs**

For Part B vs Part D medications/drugs guidelines, refer to the specific medications listed under [Guideline 3](#) below.

## 2. **Unlabeled Use of a Part B drug**

Unlabeled use of a drug may be covered only if a UnitedHealthcare Medical Director or his/her designee determines the use to be medically accepted, taking into consideration the major drug compendia. *For the list of the major drug compendia, see the [Medicare Benefit Policy Manual, Chapter 15, §50.4.3 - Unlabeled Use of Drug](#) (Accessed October 11, 2016)*

***In the case of drugs used in anti-cancer chemotherapeutic regimen, see the [Coverage Summary for Chemotherapy, and Associated Drugs and Treatments](#).***

### **Notes:**

- *The above information is for determining coverage for the unlabeled use of medication*

covered under Part B only, not Part D. Refer to the Member's Pharmacy Booklet or contact the Prescription Solutions Customer Service Department for further information on Part D coverage, if any.

- A prescription drug is a Part D drug only if it is for a medically accepted indication as defined in the Medicaid statute. This definition includes uses supported by a citation included, or approved for inclusion, in one of three compendia. These are:
  - American Hospital Formulary Service Drug Information
  - United States Pharmacopeia-Drug Information
  - DRUGDEX Information System

Based on this statutory definition, indications that are supported in peer-reviewed medical literature, but not yet reflected in one of the compendia, are not "medically accepted." Therefore, the use of a drug for such indications would not meet the definition of a Part D Drug. See the [Medicare Prescription Drug Benefit Manual Chapter 6, §10.6 - Medically Accepted Indication](#). (Accessed October 11, 2016)

- **Definition of Compendium:** Effective January 1, 2010, CMS revised the definition of "compendium" in the Medicare Benefit Policy Manual, Chapter 15, §50.4.5, to include this public transparency requirement. In this revised definition, a compendium:
  1. Includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases;
  2. Is indexed by drug or biological; and
  3. Has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

Refer to the [Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals, §50.4.5.1.A](#). (Accessed October 11, 2016)

3. **Examples medications/drugs that are covered under Part B include, but not limited to:**

a. **Durable Medical Equipment (DME) Supply Drugs**

Payment may be made for supplies that are necessary for the effective use of durable medical equipment. This includes drugs and biologicals which must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment or to assure the proper functioning of the equipment. See [Medicare Benefit Policy Manual, Chapter 15, §110.3 - Coverage of Supplies and Accessories](#). (Accessed October 11, 2016)

**Part B vs Part D Guideline:**

- 1) **Nebulizer Inhalation Drugs (e.g., albuterol sulfate, ipratropium bromide):** Certain inhalation drugs are generally covered under Part B when used with a nebulizer in the home. These drugs would not be covered under Part D for use with a nebulizer. However, if these drugs were delivered with a metered dose inhaler or other non-nebulized administration, they would be Part D drugs.

***For the list of nebulizer drugs covered under Part B, refer to the DME MAC [LCD for Nebulizers \(L33370\)](#). Compliance with these policies is required where applicable.***  
(Accessed August 8, 2017)

In the case of a member in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is

noncovered -- infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the member's "home" for this purpose. In this case, coverage for the drugs would be available under Part D.

In addition to a hospital, a SNF or a distinct part SNF, the following facilities cannot be considered a home for purposes of receiving the Medicare DME benefit:

- a nursing home that is dually-certified as both a Medicare SNF and a Medicaid nursing facility (NF);
- a Medicaid-only NF that primarily furnishes skilled care;
- a non-participating nursing home (i.e., neither Medicare or Medicaid) that provides primarily skilled care; and
- an institution which has a distinct part SNF and which also primarily furnishes skilled care.

## 2) **Infusion Pump Medications (e.g., some chemotherapeutic agents):**

In general, the supplier would bill Part B if the drug was administered using an infusion pump and bill the Part D plan for infusion using other methods (e.g., IV push). While professional services and supplies related to the administration of the infused drug are not payable under Part D, some coverage may be available under Part A or B home health benefits, under Medicaid, or from secondary commercial health benefits.

As a rule, drugs infused using an implantable pump would be covered under Part B. Drugs infused in the home using an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare DME MAC. In the case of a member in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is noncovered -- infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the member's "home" for this purpose. In this case, coverage for the drugs would be available under Part D.

In addition to a hospital, a SNF or a distinct part SNF, the following facilities cannot be considered a home for purposes of receiving the Medicare DME benefit:

- a nursing home that is dually-certified as both a Medicare SNF and a Medicaid nursing facility (NF);
- a Medicaid-only NF that primarily furnishes skilled care;
- a non-participating nursing home (i.e., neither Medicare or Medicaid) that provides primarily skilled care; and
- an institution which has a distinct part SNF and which also primarily furnishes skilled care.

See the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues](#). (Accessed October 11, 2016)

## b. **Immunosuppressive Drugs**

Immunosuppressive drug therapy following a Medicare covered organ transplant is covered.

*Note: If a supplier of the immunosuppressive drugs has not determined (or does not have documentation on file to support a determination) that either the member beneficiary did not receive an organ transplant or that the beneficiary was not enrolled in Medicare Part A as of the date of the transplant, then the supplier may not, with respect to furnishing an immunosuppressive drug: 1) bill Medicare, 2) bill or collect any amount from the beneficiary, or 3) issue an Advance Beneficiary Notice (ABN) to the beneficiary. See the [Medicare Claims Processing Manual, Chapter 17, §80.3 - Billing for Immunosuppressive Drugs](#). (Accessed October 11, 2016)*

Covered drugs include those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA. *(This is an exception to the standing drug policy which permits coverage of FDA approved drugs for nonlabeled uses, where such uses are found to be reasonable and necessary in an individual case.)*

Immunosuppressive drugs are substances that suppress or interfere with normal immune responses. They are used in controlling autoimmune diseases and in enhancing the chances for survival of foreign-tissue grafts and transplants.

Examples of FDA-approved immunosuppressive drugs include, but are not limited to:

- 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

**Notes:**

- *Prescription drugs, such as prednisone, used in conjunction with immunosuppressive drugs as part of a therapeutic regimen **are covered** as reflected in FDA approved labeling for immunosuppressive drugs. Therapeutic regimen is a combination of drugs which has been clinically recognized for the treatment of a specific type of disorder or to treat toxicities or side effects of drugs which are used at different times following an approved transplant.*
- *Immunosuppressive drugs for organ transplants **are covered** under Part B coverage except when furnished during an inpatient stay or upon discharge from the hospital, then the drugs are covered as Part A.*
- *CMS expects contractors to keep informed of FDA additions to the list of the immunosuppressive drugs.*
- *Members may have additional coverage for immunosuppressive drugs under the Part D Prescription Drug Plan which are not covered in this benefit interpretation policy. Refer to the Member's Pharmacy Booklet or contact the Prescription Solutions Customer Services Department to determine coverage eligibility for prescription drug plan benefit.*

See the [Medicare Benefit Policy Manual, Chapter 15, §50.5.1 - Immunosuppressive Drugs](#).

(Accessed October 11, 2016)

**Part B vs Part D Guideline:**

Part B would be billed if the individual had a Medicare-covered transplant; otherwise, the Part D plan would be billed.

Pharmacists would bill Part B or the individual's Part D plan based on information received from the individual or the Part D plan. Part B would be billed if the individual had a Medicare-covered transplant; otherwise, the Part D plan would be billed. (Part D plan eligibility systems could contain a marker for members who had a Medicare covered transplant. This information could come from a question included on the Part D sponsor's enrollment or coordination of benefit (COB) survey form.

In determining whether to pay for an immunosuppressive drug under Part D, it would not be appropriate for a Part D sponsor to institute a general policy of requiring a Part B claim rejection, as a substitute for maintaining information on transplant status and paying claims based on that information. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs. Instead a prior authorization requirement would be appropriate.

See the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues](#). (Accessed October 11, 2016)

Also see the [Coverage Summary for Transplants: Organ and Tissue Transplants](#).

c. **Hemophilia clotting factors**

Hemophilia clotting factors are covered for hemophilia patients competent to use such factors to control bleeding without medical supervision of factors and items related to the administration of such factors. Also see such the [Coverage Summary for Blood, Blood Products and Related Procedures and Drugs](#).

**Part B vs Part D Guideline:**

Hemophilia blood clotting factors would not be a Part D benefit because of the Part B coverage.

See the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues](#). (Accessed October 11, 2016)

d. **Oral anti-cancer drugs and Oral anti-emetics**

Oral anti-cancer drugs and oral anti-nausea (anti-emetic) drugs are covered when criteria are met. See the [Coverage Summary for Chemotherapy, and Associated Drugs and Treatments](#)

**Part B vs Part D Guideline:**

**Certain oral chemotherapy agents used in cancer treatment for which there is an infusible version of the drug.**

- Pharmacists would need to determine the reason for treatment. If related to cancer treatment, Part B would be billed; otherwise, the Part D plan should be billed.
- To the extent that a Part B-covered oral anti-cancer drug has no other medically accepted indication besides cancer treatment, Part D sponsors should not include these drugs on their formularies because of Part B coverage. For the drugs that have other medically accepted indications, prior authorization programs or other mechanisms to obtain diagnostic information could be used to ensure appropriate payment.

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

- Pharmacists would need to determine the reason for treatment. If both related to cancer treatment and a full replacement for intravenous administration within 48 hours of cancer treatment, Part B would be billed; otherwise, the Part D plan should be billed. NOTE: In order to receive Part B payment, CMS currently requires that the prescribing physician indicate on the prescription that the oral anti-emetic is being used “as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen.”
- If based on a prior authorization program or other mechanism to obtain diagnostic information, a Part D sponsor determined that a) a Part B-covered oral anti-emetic was being billed, and b) the drug was being furnished in the context of cancer treatment for use within 48 hours of cancer treatment, the Part D sponsor should deny payment. Such drugs dispensed for use after the 48-hour period, or any oral anti-emetic prescribed for conditions other than the effects of cancer treatment, would be Part D drugs.

*See the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues](#). (Accessed October 11, 2016)*

e. **Immunizations**

Immunizations (e.g., pneumococcal vaccine, Hepatitis B vaccine, and influenza vaccine) are covered when criteria are met. Refer to the [Coverage Summary for Preventive Health Services and Procedures](#) for coverage criteria.

**Part B vs Part D Guideline:**

For Hepatitis B vaccine, physicians would need to determine the level of risk of the individual. If the individual is at high or intermediate risk, Part B would be billed. For all other individuals, prior authorization programs could be used to ensure appropriate level of risk.

*See the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues](#). (Accessed October 11, 2016)*

f. **Antigens**

Antigens/antihistamines are covered when criteria are met. These are prepared by a physician (usually an allergist) for a specific patient. The physician or physician’s nurse generally administers them in the physician’s office. In some cases the physician prepares antigens and furnishes them to a patient who has been taught to self-administer them at home. Refer to the [Coverage Summary for Allergy Testing and Allergy Immunotherapy](#)

**Part B vs Part D Guideline:**

Antigens would not be a Part D benefit because of the Part B coverage. See the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues](#). (Accessed October 11, 2016)

g. **Parenteral nutrition**

Parenteral nutrition, including Intradialytic Parenteral Nutrition (IDPN), is covered under the prosthetic benefit when criteria are met. See the [Coverage Summary for Nutritional Therapy: Enteral and Parenteral Nutritional Therapy](#) for coverage criteria.

**Part B vs Part D Guideline:**

If the therapy was being provided because of a non-functioning digestive tract, Part B would be billed; if not, this would be a Part D drug. See the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues](#). (Accessed October 11, 2016)

#### h. Erythropoietin

- Epoetin alfa/EPO (*Epogen*(®) & *ProCrit*(®) and Darbepoetin alfa/DPA (*Aranesp*(®)) **are covered** for the treatment of anemia for ESRD patients who meet the Medicare coverage as outlined in the [Medicare Benefit Policy Manual, Chapter 15, §50.5.2.1 - Requirements for Medicare Coverage of EPO](#). Also see the [Medicare Benefit Policy Manual, Chapter 11, §90 - Epoetin \(EPO\)](#). (Accessed October 11, 2016)
- EPO **is covered** for hip or knee surgery candidates at high risk for preoperative transfusions with significant anticipated blood loss and who meet all of the following criteria:
  - Members with anemia and a hemoglobin between 10 and 13 mg/dL
  - Members who are not candidates for autologous blood transfusions
  - Members who are expected to lose more than 2 units of blood
  - Members who have had a work-up which indicates that their anemia appears to be that of chronic disease.

See the [Medicare Benefit Policy Manual, Chapter 15, §50.5.2.2 - Medicare Coverage of Epoetin Alfa \(Procrit\) for Preoperative Use](#). (Accessed October 11, 2016)
- EPO **is covered** to treat non-ESRD members with anemia induced by other conditions, such as chemotherapy or zidovudine (AZT) **only when** the EPO cannot be self-administered. See the [Medicare Benefit Policy Manual, Chapter 15, §50.5.2 - Erythropoietin \(EPO\)](#). (Accessed October 11, 2016)
- Erythropoiesis Stimulating Agents (ESAs) **are covered** in cancer and related neoplastic conditions **only** in accordance with Medicare criteria. See the [NCD for Erythropoiesis Stimulating Agents \(ESAs\) in Cancer and Related Neoplastic Conditions \(110.21\)](#) (Accessed October 11, 2016)

Local Coverage Determination exists for Erythropoiesis Stimulating Agents - Epoetin alfa, Darbepoetin alfa, Peginesatide. Compliance with these policies is required where applicable. These LCDs are available at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. (Accessed October 11, 2016)

#### Notes:

- **Revised Boxed Warning:** In August, 2008, Amgen submitted labeling supplements for *Epogen/Procrit* and *Aranesp* in response to FDA's Safety Labeling Change Order, issued under the authority of section 505(o)(4)(E) of the Federal Food, Drug and Cosmetic Act (FDCA). FDA approved these changes, which include the replacement of the existing Patient Package Insert with a Medication Guide and the revision of the Boxed Warning, Indications and Usage, Warnings and Dosage and Administration sections of the package insert. The approval letter and labeling can be accessed at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM109375>. (Accessed October 11, 2016)
- The Centers for Medicare & Medicaid Services (CMS) has implemented a national

*strategy for monitoring claims for the drugs epoetin alfa (Epogen®) and darbepoetin alfa (Aranesp®) for anemia management in patients with End Stage Renal Disease (ESRD) and who are dialyzed in renal facilities. For specific information, see the [MLN Matters Number 4135](#). (Accessed October 11, 2016)*

- *This article was revised on August 17, 2007 to add references to related articles. You should review MM5251 and MM5700 to see changes made to the national ESA monitoring policy (referred to as EMP). These may be viewed at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm5251.pdf> and <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5700.pdf>. (Accessed October 11, 2016)*
- *Members may have additional coverage for EPO under the Part D Prescription Drug Plan, which are not addressed in this policy. Refer to the Member's Pharmacy Booklet or contact the Prescription Solutions Customer Service Department to determine coverage eligibility for prescription drug plan benefit.*

i. **Intravenous Immune Globulin (IVIG)**

1) **Intravenous immune globulin (IVIG) in the Home**

Intravenous immune globulin (IVIG) for the treatment of primary immune deficiency diseases is **covered** in the home under Part B if **all** of the following criteria are met:

- It is an approved pooled plasma derivative for the treatment of primary immune deficiency disease; and
- The patient has a diagnosis of primary immune deficiency disease (ICD-9 codes 279.04, 279.05, 279.06, 279.12, and 279.2 or ICD-10-CM codes D80.0, D80.5, D81.0, D81.1, D81.2, D81.6, D81.7, D81.89, D81.9, D82.0, D83.0, D83.2, D83.8, or D83.9 if only an unspecified diagnosis is necessary); and
- The IVIG is administered in the home; and
- The treating physician has determined that administration of the IVIG in the patient's home is medically appropriate.

*For specific coverage criteria and benefit information, refer to the [Medicare Benefit Policy Manual, Chapter 15, §50.6 - Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home](#). (Accessed October 11, 2016)*

**Part B vs Part D Guideline:** Part B coverage for IVIG in the home is for individuals whose diagnosis is primary immune deficiency disease. Part D would provide coverage for IVIG in the home for all other medically accepted indications. Prior authorization requirements could be used to ensure appropriate payment in accordance with the Part D sponsor's medical necessity criteria. It would not be appropriate to routinely require a rejection of a claim under Part B before processing a Part D claim. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor cost.

The supplier would bill Part B if the diagnosis is primary immune deficiency disease. IVIG provided in the home for other diagnoses would be a Part D benefit. As discussed above, it would not be appropriate, as a general rule, for Part D sponsors to require a rejection of a claim under Part B before processing a Part D claim. Prior authorization

programs could be used to ensure medical necessity in accordance with the Part D sponsor's policy.

See the [Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues](#). (Accessed October 11, 2016)

Local Coverage Determinations (LCDs) exist for IVIG and compliance with these policies is required. For state-specific LCDs, see the [LCD Availability Grid \(Attachment C\)](#).

## 2) Treatment of Autoimmune Mucocutaneous Blistering Diseases

IVIg is covered for the treatment of biopsy-proven: (1) Pemphigus Vulgaris, (2) Pemphigus Foliaceus, (3) Bullous Pemphigoid, (4) Mucous Membrane Pemphigoid (a.k.a., Cicatricial Pemphigoid), and (5) Epidermolysis Bullosa Acquisita.

For more specific coverage guideline, see the [NCD for Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases \(250.3\)](#). (Accessed October 11, 2016)

Local Coverage Determinations (LCDs) exist for IVIG and compliance with these policies is required. For state-specific LCDs, see the [LCD Availability Grid \(Attachment C\)](#).

## 3) Other Indications

- Medicare does not have an NCD for other indications other than the ones outlined on #1 and #2 above.
- Local Coverage Determinations (LCDs) exist for IVIG and compliance with these policies is required. For state-specific LCDs, see the [LCD Availability Grid \(Attachment C\)](#).
- For states with no LCDs, refer to the [UnitedHealthcare Drug Policy for Immune Globulin \(IVIG and SCIG\)](#). (**IMPORTANT NOTE:** After searching the [Medicare Coverage Database](#), if no state LCD or Local Article is found, then use the above UnitedHealthcare Drug Policy.)
- Committee approval date: October 18, 2016
- Accessed August 8, 2017

## j. Intravenous Iron Therapy

Intravenous iron therapy (sodium ferric gluconate complex in sucrose injection) is covered as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. For more specific information, see the [NCD for Intravenous Iron Therapy \(110.10\)](#). (Accessed October 11, 2016)

## k. Injectable Drugs for the Treatment of Osteoporosis

Injectable drugs for the treatment of osteoporosis when provided by the home health agency and the following criteria are met:

- The member is unable to learn the skills needed to self-administer the drug, or is otherwise physically or mentally incapable of administering the drug, and that her family or caregiver are unable or unwilling to administered the drug, as documented by

- the home health agency, and
- The member sustained a bone fracture that a physician certifies was related to (post-menopausal) osteoporosis and
- The member is unable to learn the skills needed to self-administer the drug, or is otherwise physically or mentally incapable of administering the drug, and that her family or caregiver are unable or unwilling to administered the drug, as documented by the home health agency, and
- The member is homebound as defined in the Section II (Definitions) below.

See the [Medicare Benefit Policy Manual Chapter 7, §50.4.3 - Covered Osteoporosis Drugs](#). (Accessed October 11, 2016)

Also see the CMS Tips to Partners on Osteoporosis Drugs @ <http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11315-P.pdf>. (Accessed October 11, 2016)

**l. L-Dopa**

L-Dopa in the inpatient setting (hospital or SNF) **is covered** for patients with Parkinsonism that have concurrent disease(s), e.g., cardiovascular, gastrointestinal or neuropsychological.

See the [NCD for L-Dopa \(160.17\)](#) for more specific information. (Accessed October 11, 2016)

Also see [Guideline 4.d](#).

**m Dimethyl Sulfoxide (DMSO)**

Dimethyl Sulfoxide (DMSO) **is covered** only when reasonable and necessary for the treatment of interstitial cystitis. See the [NCD for Dimethyl Sulfoxide \(DMSO\) \(230.12\)](#). (Accessed October 11, 2016)

**n. Parenteral Antibiotics for the Treatment of Lyme Disease**

- Medicare does not have a National Coverage Determination (NCD) for parenteral antibiotics for the treatment of Lyme disease.
- Local Coverage Determinations (LCDs) do not exist at this time.
- For coverage guidelines, see the [UnitedHealthcare Medical Policy for Lyme Disease](#) (**IMPORTANT NOTE:** After searching the [Medicare Coverage Database](#), if no state LCD or Local Article is found, then use the above referenced policy for coverage guidelines.)
- **Committee approval date: October 18, 2016**
- Accessed October 11, 2016

**IMPORTANT NOTE:** Most medications dispensed for home infusion therapy are covered under the prescription drug benefit (Part D), not under the medical benefit (Part B). This includes members who have Medicare Advantage and Medicare Part D products and receive infusion therapies at their regular residence, including those permanently residing in a skilled nursing facility, or a stand-alone infusion center. It does not impact infusion therapies provided during a hospital stay or short-term stay at a skilled nursing facility.

Most home infusion services will require prior authorization. To authorize these services, uses the established protocol based upon your contractual relationship with UnitedHealthcare and/or its affiliates, or call the Provider Services phone number listed on the back of the

member identification card.

**o. Botulinum Toxin for the Treatment of Migraine Headaches**

- Medicare does not have a National Coverage Determination (NCD) for Botulinum Toxins.
- Local Coverage Determinations (LCDs) for Botulinum Toxins which address the treatment of migraine headaches exist and compliance with this LCD is required where applicable. Refer to the state-specific LCDs for coverage guidelines and coding payment; see the [LCD Availability Grid \(Attachment A\)](#) for state-specific LCDs.
- **For states with no LCDs**, see the [UnitedHealthcare Drug Policy for Botulinum Toxins A and B](#) for coverage guidelines. (**IMPORTANT NOTE:** After searching the [Medicare Coverage Database](#), if no state LCD or Local Article is found, then use the above referenced policy for coverage guidelines.)
- **Committee approval date: October 18, 2016**
- Accessed August 8, 2017

**p. Denosumab (Xgeva®, Prolia®)**

Denosumab (Xgeva®) can be used for chemotherapeutic indications and Denosumab (Prolia®) can be used as well as for non-chemotherapeutic indications. For chemotherapeutic indications, refer to the [Coverage Summary for Chemotherapy, and Associated Drugs and Treatments](#)

- Medicare does not have a National Coverage Determination (NCD) for Denosumab (Xgeva®).
- Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) exist and compliance with these LCDs and LCAs is required where applicable. For state specific LCDs/LCAs, see the [LCD/LCA Availability Grid \(Attachment D\)](#).
- **For states with no LCDs or LCAs**, refer to [Guideline 1](#) and [Guideline 2](#) above for Medicare guidelines for covered indications. (**IMPORTANT NOTE:** After checking the LCD/LCA Availability Grid and searching the [Medicare Coverage Database](#), if no state LCD or Local Article is found, Coverage Summary Guidelines above.)
- **Committee approval date: October 18, 2016**
- Accessed June 1, 2017

**q. Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS)**

Effective for claims with dates of service on and after March 23, 2010, dermal injections for LDS are **only reasonable and necessary** using dermal fillers approved by the Food and Drug Administration (FDA) for this purpose, and then only in HIV-infected beneficiaries when LDS caused by antiretroviral HIV treatment is a significant contributor to their depression. See the [NCD for Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome \(LDS\) \(250.5\)](#). (Accessed October 11, 2016)

**r. Rituximab (Rituxan®)**

Rituximab (Rituxan®) can be used for chemotherapeutic indications as well as for non-chemotherapeutic indications. (**For chemotherapeutic indications, refer to the [Coverage Summary for Chemotherapy, Associated Drugs and Treatments](#).**)

- Medicare does not have a National Coverage Determination (NCD) for Rituximab (Rituxan®)

- *Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) exist and compliance with these LCDs and LCAs is required where applicable. For state specific LCDs/LCAs, see the [LCD/LCA Availability Grid \(Attachment B\)](#).*
- ***For states with no LCDs or Local Articles, see the [UnitedHealthcare Drug Policy for Rituxan® \(rituximab\)](#) with individual consideration for the following diagnoses:***
  - *Waldenstrom's Macroglobulinemia*
  - *Multiple Sclerosis relapsing, remitting (RRMS) (as a third line therapy)*
- ***(IMPORTANT NOTE: After searching the [Medicare Coverage Database](#), if no state LCD or LCA is found, then use the above referenced policy for coverage guidelines.)***
- ***Committee approval date: October 18, 2016***
- *Accessed August 8, 2017*

s. **Milrinone (Primacor®)-Use in Home Setting**

- *Medicare does not have a National Coverage Determination (NCD) for Milrinone (Primacor®)*
- *All states have **DME MAC Local Coverage Determinations (LCDs)** for Milrinone (Primacor®) for home setting and compliance with these LCDs is required where applicable.*
- ***For coverage guidelines for use in the home, see the [DME MAC LCDs for External Infusion Pumps](#). For state-specific LCDs, see the [LCD Availability Grid \(Attachment E\)](#).***
- ***Committee approval date: October 18, 2016***
- *Accessed August 8, 2017*

**IMPORTANT NOTE: There are safety and efficacy issue regarding the use of Milrinone in the home setting. Please read LCDs before authorizing.**

t. **Drugs Treated as Hospital Outpatient Supplies**

In certain circumstances, Medicare pays for drugs that may be considered usually self-administered by the patient when such drugs function as supplies. This is the case when the drugs provided are an integral component of a procedure or are directly related to it, i.e., when they facilitate the performance of or recovery from a particular procedure. Except for the applicable copayment, hospitals may not bill beneficiaries for these types of drugs because their costs, as supplies, are packaged into the payment for the procedure with which they are used. Listed below are examples of when drugs are treated as supplies and hospitals should bill Medicare for the drug as a supply and should not separately bill the member.

- Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure
- Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre-and postoperatively.
- Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure
- Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp
- Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure

The following are examples of when a drug is not directly related or integral to a procedure, and does not facilitate the performance of or recovery from a procedure. Therefore the drug is not considered a packaged supply. In many of these cases the drug itself is the treatment instead of being integral or directly related to the procedure, or facilitating the performance of or recovery from a particular procedure.

- Drugs given to a patient for his or her continued use at home after leaving the hospital
- Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment
- Daily routine insulin or hypertension medication given preoperatively to a patient
- A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain
- A laxative suppository for constipation while the patient waits to receive an unrelated X-ray

*These two lists of examples may serve to guide hospitals in deciding which drugs are supplies packaged as a part of a procedure, and thus may be billed under Part B. Hospitals should follow CMS' guidance for billing drugs that are packaged and paid as supplies, reporting coded and uncoded drugs with their charges under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs*

*See the [Medicare Benefit Policy Manual, Chapter 15, §50.2 - Determining Self-Administration of Drug or Biological, M – Drugs Treated as Hospital Outpatient Supplies](#). (Accessed October 11, 2016)*

u. **Testopel® (testosterone pellet) (CPT codes 11980 and S0189)**

- Medicare does not have a National Coverage Determination (NCD) for Testopel® (testosterone pellet).
- Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) exist and compliance with these LCDs and LCAs is required where applicable. For state specific LCDs/LCAs, see the [LCD/Local Articles Availability Grid \(Attachment F\)](#).
- For states with no LCDs or LCAs, see the First Coast [LCD for Testosterone Pellets \(Testopel®\) \(L33412\)](#) Also refer to [Section II Definitions](#) for the definition of "Self-administered drug". (IMPORTANT NOTE: After checking the LCD Availability Grid and searching the [Medicare Coverage Database](#), if no state LCD or LCA is found, then use the above referenced policy.)
- **Committee approval date: October 18, 2016**
- Accessed August 8, 2017

**FDA Warning Letter:** In 2010, the FDA issued a warning letter/notice for Testopel® (testosterone pellet). This information is available at.

<http://www.fdanews.com/ext/resources/files/archives/s/SlatePharma.pdf>. (Accessed October 11, 2016)

4. **Examples of medications/drugs that are not covered:**

a. **Vitamin B12 Injections**

Vitamin B12 injections to strengthen tendons, ligaments, etc., of the foot are not covered under Medicare because (1) there is no evidence that vitamin B12 injections are effective for

the purpose of strengthening weakened tendons and ligaments, and (2) this is nonsurgical treatment under the subluxation exclusion. Accordingly, Vitamin B12 injections are not considered reasonable and necessary.

See the [NCD for Vitamin B12 Injections to Strengthen Tendons, etc., of the Foot \(150.6\)](#) (Accessed October 11, 2016)

**b. Nesiritide for Heart Failure**

Nesiritide for heart failure is not covered. See the [NCD for Nesiritide for Treatment of Heart Failure Patients \(200.1\)](#) (Accessed October 11, 2016)

**c. Laetrile**

Laetrile and the other drugs called by the various terms mentioned below, used primarily in the treatment or control of cancer, **are not covered**. Although the terms "Laetrile," "laetrile," "amygdalin," "Sarcarcinase," "vitamin B-17," and "nitrososide" have been used interchangeably, the chemical identity of the substances to which these terms refer has varied.

For more specific information, see the [NCD for Laetrile and Related Substances \(30.7\)](#). (Accessed October 11, 2016)

**d. Outpatient L-Dopa**

Outpatient L-Dopa **is not covered because** it is a self-injectable medication, unless the member has Part D pharmacy benefit coverage. See the [NCD for L-Dopa \(160.17\)](#) for more specific information. (Accessed October 11, 2016)

Also see [Guideline 3.1](#).

**e. Investigational or experimental drugs** are not covered. See the [Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials](#)

**f. Placebos** are not covered.

**g. Outpatient Prescription Drugs**

Outpatient prescription drugs are not covered except those medications/drugs covered under the Member's Part D Prescription Drug Plan benefit. Refer to the Member's Pharmacy Program booklet or contact the Prescription Solutions Customer Services Department to determine coverage eligibility for Part D Prescription Drug benefit.

**h. Medications for the Treatment of Sexual Dysfunction**

Medications for the treatment of sexual dysfunction including erectile dysfunction, impotence, anorgasm or hypoorgasm are not covered. Also see the [Coverage Summary for Impotence Treatment](#)

**i. Medications for Elective Enhancement**

Medications for elective enhancement, such as those used for weight loss, hair growth, sexual performance, athletic performance, cosmetic purposes, anti-aging, and mental performance are not covered. Also see the [Coverage Summary for Cosmetic and Reconstructive Procedures](#).

**j. Drugs included in the CMS Self-administered Drug Exclusion List**

Drugs included in the CMS Self-administered Drug Exclusion List are **not covered**.

Notes:

- **Self-Administered Drug (SAD) Exclusion List Report:** Local Contractors have self-administered drugs exclusion lists. Compliance with these lists is required where applicable. The Self-Administered Drug (SAD) Exclusion List Report is available at <http://www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3d%3d&>. (Accessed October 11, 2016)
- **PCSK9 Inhibitors**  
PCSK9 Inhibitors, i.e., Praluent™ (alirocumab) and Repatha™ (evolocumab) are considered self-administered drugs and are not covered under the Part B medical benefit. Refer to the Member's Pharmacy Program booklet or contact the Prescription Solutions Customer Service Department to determine coverage eligibility for this drugs under the Part D Prescription Drug benefit.

k. **Off-Label/unlabeled Drug Use**

Off-Label/unlabeled drug use **is not covered** unless criteria are met; see [Guideline 2](#) above for coverage criteria and guidelines.

5. **Other Specific Medications not listed above:**

- a) Check for available LCDs or LCAs at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search.asp&>.
- b) If there are no applicable LCDs or Local Articles found, refer to [Guideline 1](#) and [Guideline 2](#) of this Coverage summary for Medicare guidelines for covered Part B medications and the use of compendia and evidence-based medical literature in determining coverage for specific medication.

6. **Shortage of Leucovorin (J0640)**

There is currently a nationwide shortage of injectable racemic leucovorin, available only as a generic drug and only from two manufacturers in the US (Bedford Laboratories and Teva Pharmaceuticals). According to the FDA, the shortages are due to manufacturing delays; however, the American Society of Health-System Pharmacists (ASHP) reports that Bedford cannot provide a reason for the shortage. Information on current availability of specific vial sizes and expected release dates for others can be found on the [FDA website](#) and [American Society of Health-System Pharmacists \(ASHPCurrent Drug Shortage Bulletin\)](#). (Accessed October 11, 2016)

For patients affected by this shortage, the UnitedHealthcare will consider levoleukovorin (J0641) as an alternative for leucovorin (J0640).

Refer to [Coverage Summary for Chemotherapy, and Associated Drugs and Treatments](#) for information on Chemotherapy Drugs.

## II. DEFINITIONS

**FDA Approved Drug:** A drug that has received final marketing approval by the Food and Drug Administration (FDA) and as a part of its labeling contains its recommended uses and dosages as well as adverse reactions and recommended precautions in using it. [Medicare Benefit Policy Manual, Chapter 15, §50.4.2 - Unlabeled Use of Drug](#). (Accessed October 11, 2016)

**Hemophilia:** For purposes of Medicare Part B coverage, hemophilia encompasses the following conditions:

- Factor VIII deficiency (classic hemophilia);
- Factor IX deficiency (also termed plasma thromboplastin component (PTC) or Christmas factor deficiency); and
- Von Willebrand's disease

[Medicare Benefit Policy Manual, Chapter 15, §50 Drugs and Biologicals.](#) (Accessed October 11, 2016)

**Homebound:** The restricted ability of a member, due to an illness or injury, to leave home without the assistance of another or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if leaving the home is medically contraindicated. A person does not need to be bedridden to be confined to the home. However, the physical condition must be such that there exists a normal inability to leave home and leaving requires a considerable and taxing effort.

If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment.

Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration.

Generally speaking, a patient will be considered to be homebound if they have a condition due to an illness or injury that restricts their ability to leave their place of residence except with the aid of: supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person; or if leaving home is medically contraindicated.

[Medicare Benefit Policy Manual, Chapter 15, §50 Drugs and Biologicals.](#) (Accessed October 11, 2016)

**Not usually self-administered by the patient (as defined by Medicare):**

- Administered:** The term administered refers only to the physical process by which the drug enters the patient's body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Only injectable (including intravenous) drugs are eligible for inclusion under the "incident to" benefit. Other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are all considered to be usually self-administered by the patient.
- 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. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and you may not make any Medicare payment for it.
- By the patient:** The term "by the patient" means Medicare beneficiaries as a collective whole. Include only the patients themselves and not other individuals (which do not include spouses, friends, or other caregivers). [Medicare Benefit Policy Manual, Chapter 15, §50.2 Determining Self-Administration of Drug or Biological.](#) (Accessed October 11, 2016)

**Unlabeled Use of Drug:** A use that is not included as an indication of the drug's label as approved by FDA. [Medicare Benefit Policy Manual, Chapter 15, §50.4.2 - Unlabeled Use of Drug.](#) (Accessed October 11, 2016)

### III. REFERENCES

See above

#### IV. REVISION HISTORY

- 10/18/2016 Annual review with the following recommended updates:
- Guideline 2 (Unlabeled Use of Part B Medications/Drugs)
- Deleted the outdated list of compendia and add a reference link to the Medicare Benefit Policy Manual section which has the most current list
  - Deleted the section titled “*In determining off-label/unlabeled drug use appropriateness consider the following*”. The referenced Medicare Benefit Policy Manual no longer has this specific section.
  - Under the definition of compendium – deleted the reference link to the CMS Manual Transmittal 120 Revision of Definition of Compendia as Authoritative Source for Use in the Determination of a Medically-Accepted Indication of Drugs/Biologicals Used Off-label in Anti-Cancer chemotherapeutic Regimens; transmittal info already included in the referenced Medicare Benefit Policy manual.
- Guideline 4.h (Medications for the Treatment of Sexual Dysfunction) – deleted “*(other than the single dose of MUSE as described above)*” as there is no information about MUSE included in this policy.
- 06/21/2016 Re-review with the following update:
- Guideline 3.i (Intravenous immune globulin (IVIG) in the Home) - Added the following “or ICD-10-CM codes D80.0, D80.5, D81.0, D81.1, D81.2, D81.6, D81.7, D81.89, D81.9, D82.0, D83.0, D83.2, D83.8, or D83.9 if only an unspecified diagnosis is necessary)”
- 04/19/2016 Re-review; no updates to the guideline content; updated reference link(s) of the applicable LCDs to reflect the condensed link.
- 11/17/2015 Annual review with no updates.
- 10/20/2015 Re-review with the following recommended update:
- Guideline 4j (Drugs included in the CMS Self-administered Drug Exclusion List)
- Updated to include the following statement:  
*PCSK9 Inhibitors, i.e., Praluent™ (alirocumab) and Repatha™ (evolocumab) are considered self-administered drugs and are not covered under the Part B medical benefit. Refer to the Member’s Pharmacy Program booklet or contact the Prescription Solutions Customer Service Department to determine coverage eligibility for this drugs under the Part D Prescription Drug benefit.*
- 08/18/2015 Guideline 3 (Immunosuppressive Drug Therapy)
- Added coverage guidelines for immunosuppressive drugs (moved from the Organ Transplant Coverage Summary) based on the Medicare Benefit Policy Manual, Chapter 15, § 50.5.1 - Immunosuppressive Drugs

- Added the following note to clarify coverage of immunosuppressive drugs based on the Medicare Claims Processing Manual, Chapter 17, §80.3 - Billing for Immunosuppressive

*If a supplier of the immunosuppressive drugs has not determined (or does not have documentation on file to support a determination) that either the member beneficiary did not receive an organ transplant or that the beneficiary was not enrolled in Medicare Part A as of the date of the transplant, then the supplier may not, with respect to furnishing an immunosuppressive drug: 1) bill Medicare, 2) bill or collect any amount from the beneficiary, or 3) issue an Advance Beneficiary Notice (ABN) to the beneficiary.*

- 05/19/2015 Guideline 4.a [Testopel™ (testosterone pellet)]
- Moved from Guideline 4.a (Examples of medications/drugs that are not covered) to Guideline 3.u (Examples medications/drugs that are covered)
  - Added Attachment F [LCD Availability Grid for Hormone Pellets (Testopel™)]
- 03/12/2015 Formatting change only.
- 02/17/2015 Guideline 1.a (Part B Medications/Drug) - Added language to indicate: *Coverage is usually limited to drugs or biologicals administered by infusion or injection. However, if the injection is generally self-administered (e.g., Imetrix), it is not covered under Part B. Despite the general limitation on coverage for outpatient drugs under Part B, some self-administered medications/drugs are also covered.*
- Guideline 1.b (Part D Medications/Drugs) - Added language to indicate: *A Part D covered drug are available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication. A drug for which coverage is available under Part A or Part B, as it is being “prescribed and dispensed or administered” with respect to the individual, is excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage. CMS interprets this to mean that if payment could be available under Part A or Part B to the individual for such drug, then it will not be covered under Part D*
- Some members may have coverage for Part D drugs under UniteHealthcare. Refer to the Member’s Pharmacy Booklet or contact the Prescription Solutions Customer Service Department to determine coverage eligibility for Part D prescription drug plan benefit.*
- For Medicare’s detailed coverage information for medications/drugs under Part D, refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, §10 Definition of Part D Drugs at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf>.*
- Guideline 1.c (Part B vs Part D Medications/Drugs) - Added language to indicate: For Part B vs Part D medications/drugs guideline, refer to the specific medications listed under [Guideline #3](#) below.
- Guideline 3.a (Durable Medical Equipment Supply Drugs)
- Added Guideline 3.a.1 (Nebulizer Inhalation Drugs) and Guideline 3.a.2 (Infusion Pump Medications (e.g., some chemotherapeutic agents))

- Added Part B vs Part D guideline based on the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues

Part B vs Part D guideline based on the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues added to the following sections:

- Guideline3.b (Immunosuppressive drug therapy) -
- Guideline3.c (Hemophilia clotting factors)
- Guideline3.d [Oral anti-cancer drugs and oral anti-nausea (anti-emetic) drugs]
- Guideline3.e (Immunizations)
- Guideline3.f (Antigens/antihistamines)
- Guideline3.i.1 [Intravenous immune globulin (IVIG) in the Home]

Guideline3.g (Parenteral Nutrition)

- Added language to indicate:  
*Parenteral nutrition, including Intradialytic Parenteral Nutrition (IDPN), is covered under the prosthetic benefit when criteria are met. See the [Coverage Summary for Nutritional Therapy: Enteral and Parenteral Nutritional Therapy](#) for coverage criteria.*
- Added Part B vs Part D guideline based on the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C - Medicare Part B versus Part D Coverage Issues

Guideline3.i.2 (Treatment of Autoimmune Mucocutaneous Blistering Diseases) - Removed specific guideline; there is a reference link to the NCD for Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (250.3) which has specific guidelines

Guideline 4.k (Drugs included in the CMS Self-administered Drug Exclusion List) - Updated the reference link to the Self-Administered Drug (SAD) Exclusion List Report

Guideline 5 (Other Specific Medications not listed above) - Added guideline to indicate:

- Check for available LCDs or Local Articles at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search.asp&>.*
- If there are no applicable LCDs or Local Articles found, refer to [Guidelines #1](#) and [Guidelines #2](#) of this Coverage summary for Medicare guidelines for covered Part B medications and the use of will ia and evidence-based medical literature in determining coverage for specific medication.*

11/18/2014 Annual review with the following updates:

Guideline 1 [Outpatient (Part B) Medications/Drug] - Removed note pertaining to payment for injectables

Guideline 3 (Examples medications/drugs that are covered) - Updated title to include “under Part B”

Guideline 3.d (Small Volume Nebulizer Medications/Drugs)

- Updated to include large nebulizer
- Added reference link to the Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid

Guideline 3.k.3 [Intravenous Immune globulin (IVIG)/Other Indications]

- Added language to indicate: *Coverage guidelines of the available LCDs do not align; there is no uniformity. The UnitedHealthcare Drug policy for UnitedHealthcare Drug Policy for Immune Globulin (IVIG and SCIG) does not align with the available LCDs.*

Guideline 3.n (Botulinum Toxin for the Treatment of Migraine Headaches)

- Added language to indicate:  
*Coverage guidelines of the available LCDs align (covered) and cover more than 80% of the geographic area; there is uniformity. The UnitedHealthcare Medical Policy guidelines align (proven) with the available LCD guidelines*
- Changed default guideline for states with no LCDs from *National Government Services LCD for Botulinum Toxins (L26841)* to the *UnitedHealthcare Drug Policy for Botulinum Toxins A and B*

Guideline 3.o Denosumab (Xgeva®, Prolia ®)

- Added language to indicate: *Coverage guidelines of the available LCDs align and cover less than 80% of the geographic area; there no uniformity. A UnitedHealthcare Drug Policy does not exist at this time.*

Guideline 3.q Rituximab (Rituxan®)

- Added language to indicate:  
*Coverage guidelines of the available LCDs do not align; there is no uniformity. UnitedHealthcare Drug policy for Rituxan does not align with the available LCDs.*
- Changed default guideline for states with no LCDs from *National Government Services Article RITUXIMAB (Rituxan®) (A49636)* to the *UnitedHealthcare Medical Policy for Rituxan (rituximab) with individual consideration for the following diagnoses:*
  - *Waldenstrom's Macroglobulinemia*
  - *Multiple Sclerosis relapsing, remitting (RRMS) (as a third line therapy)*

Guideline 3.r [Milrinone (Primacor®) - Use in Home Setting]

- Added language to indicate: *Coverage guidelines of the available LCDs align and cover more than 80% of the geographic area; with uniformity. A UnitedHealthcare Drug policy does not exist at this time.*

Guideline 4.a [Testopel™ (testosterone pellet)]

- Added language to indicate:  
*A UnitedHealthcare Drug policy does not exist at this time.*

10/21/2014 Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.

06/17/2014 Re-review with the following updates:

- Guideline #3.r-Milrinone (Primacor®)-Deleted guideline for use outside of home setting"; default Novitas LCD for Outpatient Intermittent Inotropic Therapy for Heart Failure (L32699) which is the only available LCD, was retired on October 31, 2013
- Deleted following definitions (no CMS reference available): Epoietin, Epoietin alfa (EPO) and darbepoetin alfa (Aranesp), Erythropoietin, Hematocrit (Hct), Hemoglobin (Hgb), Immunosuppressive drugs and Therapeutic regimen
- Added applicable CMS reference to the following definitions: FDA approved drug,

- Not usually self-administered by the patient and Unlabeled use of drug
  - Updated the definitions of Hemophilia and Homebound (based on the applicable reference NCD)
- 02/18/2014 Deleted reference and link to the UnitedHealthcare Home Infusion Coverage document
- 12/17/2013 Annual review with the following update:
- Guideline #3.a (Erythropoietin)-Deleted the following language as the reference/link for this information is no longer available
  - Local Carriers have implemented a change not to cover ESA for the treatment of anemia of cancer, i.e., anemia due to cancer process itself. Chemotherapy induced anemia will continue to be covered. The following American Society of Clinical Oncology (ASCO) website provides the *Summary of Decision Activity of the Local Carriers*.
- 08/20/2013 Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g)
- 02/19/2013 Guidelines #4.a (Testopel®) revised; changed the default guidelines for states with no Local Coverage Determinations (LCDs), from FDA Approved Indications to the First Coast LCD for Testosterone pellets (Testopel®) (L33002)
- 12/17/2012 Annual review with the following updates:
- Guidelines 3.r (Milrinone/outside of home setting) updated; the default LCD for states with no LCDs, L30772 was retired on 08/12/2012 due to the MAC transition from Pinnacle to Novitas; default LCD for states with no LCDs replaced with the corresponding Novitas LCD, L32699. No change in guidelines
  - Guidelines 3.s (Drugs Treated as Hospital Outpatient Supplies) added
  - Guidelines #4.a Testopel™ (testosterone pellet) revised, i.e., basis for coverage guidelines changed to the FDA indications as the LCDs/Articles for Testopel™ are no longer available at this time.
- 08/16/2012 Guidelines #1 updated the link to the Medicare Part B versus Part D Coverage Issues Guidelines #4.a updated to include the corrected link to the FDA warning letter/notice for Testopel™
- 06/18/2012 Revised to include Guidelines # 4.a Testopel™ (testosterone pellet)
- 02/27/2012 Revised to include Guidelines # 3.r Milrinone (Primacor®)
- 01/01/2012 The Infusion Coverage Criteria Grid UnitedHealthcare Home (Attachment A) Part B was updated to include Gammagard and Gamunex under the Therapeutic Class “Immune Globulin Subcutaneous”
- 11/18/2011 Annual review with the following updates:
- Coverage Summary Index was added
  - Guidelines #3.k.3 (Other Indications for IVIG) and Guidelines #3.o (Denosumab) added
  - Guidelines #3.p (Sipuleucel-T) deleted; moved to the CS for Chemotherapy
  - Guidelines #3.m was changed from “IV antibiotics” to “Parenteral antibiotics.”

- Attachment B (LCD Availability Grid for Botulinum Toxins), Attachment C (LCD Availability Grid for Rituximab) were updated

- 06/30/2011 Guidelines #3.r Rituximab (Rituxan®) added
- 05/09/2011 Attachment A – UnitedHealthcare Home Infusion Part B Coverage Criteria updated
- 04/26/2011 Annual review; Guidelines #3.q (PROVENGE®) added
- 02/21/2011 Guidelines #3.o – Toxin for the Treatment of Migraine Headaches revised using the standard Coverage Summary language format and using L26841 for states with no LCDs
- 08/24/2010 Guidelines #1 updated to include a note requiring a primary diagnosis code for the payment of injectable medications. A note regarding the shortage of shortage of Leucovorin (J0640) was also added.

## V. ATTACHMENT(S)

Attachment A - LCD Availability Grid				
<u>Botulinum Toxins for the Treatment of Migraine Headaches</u>				
CMS website accessed August 8, 2017				
IMPORTANT NOTE: Use the applicable LCD based on member's residence/place of service AND type of service.				
LCD ID	LCD Title	Contractor Type	Contractor	States
L33274	<a href="#">Botulinum Toxins</a>	A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L33646	<a href="#">Botulinum Toxins</a>	MAC - Part A and B	National Government Services, Inc.	IL, MN, WI CT, NY, ME, MA, NH, RI, VT
L33949	<a href="#">Botulinum Toxins</a>	MAC - Part A and B	CGS Administrators, LLC	KY, OH
L34253	<a href="#">Drugs and Biologicals: Botulinum Toxins</a>	MAC - Part A and B	Cahaba Government Benefit Administrators®, LLC	AL, GA, TN
L34635	<a href="#">Botulinum Toxin Type A &amp; Type B</a>	MAC - Part A and B	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE
L34635	<a href="#">Botulinum Toxin Type A &amp; Type B</a>	MAC - Part A and B	Wisconsin Physicians Service Insurance Corporation	AK, AL, AR, AZ, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, OH, OR, RI, SC, SD, TN, UT, VA, VI, VT, WA, WI, WV, WY
L35170	<a href="#">Botulinum Toxin Types A and B Policy</a>	A and B MAC	Noridian Healthcare Solutions, LLC	CA, AS, GU, HI, MP, NV
L35172	<a href="#">Botulinum Toxin Types A and B</a>	A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA, AZ, MT, ND, SD, UT WY
<b>End of Attachment A</b>				

Attachment B - LCD Availability Grid				
<u>Rituximab (Rituxan®)</u>				
CMS website accessed August 8, 2017				
IMPORTANT NOTE: Use the applicable LCD based on member's residence/place of service AND type of service.				
LCD ID	LCD Title	Contractor Type	Contractor	States
A52452	<a href="#">Rituximab (Rituxan®) -</a>	MAC - Part A and B	National Government	IL, MN, WI

**Attachment B - LCD Availability Grid**  
[Rituximab \(Rituxan®\)](#)

CMS website accessed August 8, 2017

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

LCD ID	LCD Title	Contractor Type	Contractor	States
	<a href="#">Related to LCD L33394</a>		Services, Inc.	CT, NY, ME, MA, NH, RI, VT
L33746	<a href="#">Rituximab (Rituxan®)</a>	A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L34306	<a href="#">Drugs and Biologicals: Rituximab (Rituxan®)</a>	A and B MAC	Cahaba Government Benefit	AL, GA, TN
L35026	<a href="#">Rituximab (Rituxan®)</a>	A and B and HHH MAC	Palmetto GBA	SC, VA, WV, NC

**End of Attachment B**

**Attachment C - LCD Availability Grid**  
[Intravenous Immune Globulin \(IVIG\)](#)

CMS website accessed August 8, 2017

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

LCD ID	LCD Title	Contractor Type	Contractor	States
L34007	<a href="#">Intravenous Immune Globulin</a>	A and MAC	First Coast Service Options, Inc.	FL, PR, VI
L33610	<a href="#">Intravenous Immune Globulin</a>	DME MAC	Noridian Healthcare Solutions, LLC (16013)	CT, DC, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT
			CGS Administrators, LLC (18003)	AL, AR, CO, FL, GA, LA, MS, NC, NM, OK, PR, SC, TN, TX, VA, VI, WV
			Noridian Healthcare Solutions, LLC (19003)	AK, AS, AZ, CA, GU, HI, IA, ID, KS, MO, MT, ND, NE, MP, NV, OR, SD, UT, WA, WY
			CGS Administrators (17013)	IL, IN, KY, MI, MN, OH, WI
L34771	<a href="#">Immune Globulins</a>	MAC Part A and B	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE
L34771	<a href="#">Immune Globulins</a>	MAC Part A	Wisconsin Physicians Service Insurance Corporation	AK, AL, AR, AZ, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, OH, OR, RI, SC, SD, TN, UT, VA, VI, VT, WA, WI, WV, WY
A52446	<a href="#">Local Coverage Article: Intravenous Immune Globulin (IVIG) - Related to LCD L33394</a>	MAC Part A and B A and B MAC	National Government Services, Inc.	CT, IL, MA, ME MN, NH, NY, RI, VT, WI
L34256	<a href="#">Drugs and Biologicals: Immune Globulin Intravenous (IVIg)</a>	MAC - Part A and B	Cahaba Government Benefit Administrators®, LLC	AL, GA, TN
L35093	<a href="#">Intravenous Immune Globulin (IVIG)</a>	A and B MAC	Novitas Solutions, Inc.	CO, NM, OK, TX, AR, LA, MS DE, DC, MD, NJ, PA
L34074	<a href="#">Immune Globulin Intravenous (IVIg)</a>	A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA, AZ, MT, ND, SD, UT WY
L34314	<a href="#">Immune Globulin Intravenous (IVIg)</a>	A and B MAC	Noridian Healthcare Solutions, LLC	CA, AS, GU, HI, MP, NV

**Attachment C - LCD Availability Grid**  
**Intravenous Immune Globulin (IVIG)**

CMS website accessed August 8, 2017

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

LCD ID	LCD Title	Contractor Type	Contractor	States
L34580	<a href="#">Intravenous Immunoglobulin (IVIG)</a>	A and B and HHH MAC	Palmetto GBA	SC, VA, WV, NC
L35891	<a href="#">Intravenous Immune Globulin</a>	A and B MAC	CGS Administrators, LLC	KY, OH

**End of Attachment C**

**Attachment D – LCD Availability Grid**  
**Denosumab (Prolia®, Xgeva®)**

CMS website accessed August 8, 2017

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

LCD ID	LCD Title	Contractor Type	Contractor	States
A52399	<a href="#">Local Coverage Article: Denosumab (Prolia™, Xgeva™) - Related to LCD L33394</a>	MAC - Part A and B A and B and HHH MAC	National Government Services, Inc.	IL, MN, WI CT, NY, ME, MA, NH, RI, VT
A52424	<a href="#">Local Coverage Article: Denosumab (Prolia™, Xgeva™)</a>	MAC - Part A and B	CGS Administrators, LLC	KY, OH
L33270	<a href="#">Bisphosphonates (Intravenous [IV]) and Monoclonal Antibodies in the Treatment of Osteoporosis and Their Other Indications</a>	A and B MAC	First Coast Service Options, Inc.	FL, PR, VI

**End of Attachment D**

**Attachment E - LCD Grid Availability**  
**Milrinone (Primacor®) - Home Setting**

CMS website accessed August 8, 2017

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

LCD ID	LCD Title	Contractor Type	Contractor	States
L33794	<a href="#">External Infusion Pumps</a>	DME MAC	Noridian Healthcare Solutions, LLC (16013)	CT, DC, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT
			CGS Administrators, LLC L33794 (18003)	AL, AR, CO, FL, GA, LA, MS, NC, NM, OK, PR, SC, TN, TX, VA, VI, WV
			Noridian Healthcare Solutions, LLC (19003)	AK, AS, AZ, CA, GU, HI, IA, ID, KS, MO, MT, ND, NE, MP, NV, OR, SD, UT, WA, WY
			CGS Administrators (17013)	IL, IN, KY, MI, MN, OH, WI

**End of Attachment E**

**Attachment F - LCD Availability Grid****Hormone Pellets (Testopel®)**

CMS website accessed August 8, 2017

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

<b>LCD ID</b>	<b>LCD Title</b>	<b>Contractor Type</b>	<b>Contractor</b>	<b>States</b>
L35658	<a href="#">Surgery: Implantable Hormone Pellets</a>	MAC - Part A and B	Cahaba Government Benefit	AL, GA, TN
L33412	<a href="#">Testosterone pellets (Testopel®)</a>	A and B MAC	First Coast Service Options, Inc.	FL, PR, VI
L36569	<a href="#">Treatment of Males with Low Testosterone</a>	A and B MAC	Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, WA, SD, UT WY
L36538	<a href="#">Treatment of Males with Low Testosterone</a>	A and B MAC	Noridian Healthcare Solutions, LLC	CA, AS, GU, HI, MP, NV

**End of Attachment F**