Medications/Drugs (Outpatient/Part B)

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Instructions for Use

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- Lucentis® (Ranibizumab)
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- Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot (NCD 150.6)
- Xgeva®, Prolia® (Denosumab)

Coverage Guidelines

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 Coverage Summary titled Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.

COVID-19 Public Health Emergency Waivers & Flexibilities: In response to the COVID-19 Public Health Emergency, CMS has updated some guidance for certain respiratory services. For a comprehensive list of Coronavirus Waivers & Flexibilities, refer to https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers. (Accessed September 15, 2021)

Outpatient Medications/Drugs

Part B Medications/Drugs

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". Refer to the definition of Not Usually Self-Administered by the 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. For examples, refer to the Medications/Drugs Covered Under Part B and Medications/Drugs Not Covered sections.

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 September 15, 2021)

Part D Medications/Drugs

A Part D covered drug is 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.

Section 1860D-2(e)(4) of the Act defines "medically-accepted indication," in part by reference to section 1927(k)(6) of the Act, to any use of a covered Part D drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. The recognized compendia are:

- American Hospital Formulary Service Drug Information, and
- DRUGDEX® Information System

Refer to the Medicare Prescription Drug Benefit Manual Chapter 6, §10.6 – Medically Accepted Indication. (Accessed September 15, 2021)

Note: 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 September 15, 2021)

Part B vs. Part D Medications/Drugs

For Part B vs. Part D medications/drugs guidelines, refer to the specific medications listed under the Medications/Drugs Covered Under Part B section.

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, authoritative medical literature and/or accepted standards of medical practice.

Refer to the Medicare Benefit Policy Manual, Chapter 15, §50.4.2 – Unlabeled Use of Drug. (Accessed September 15, 2021)

For the list of the major drug compendia, refer to the Medicare Benefit Policy Manual, Chapter 15, §50.4.5.B – Recent Revision to Compendia List. (Accessed September 15, 2021)

In the case of drugs used in anti-cancer chemotherapeutic regimen, refer to the Coverage Summary titled 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.
- Definition of Compendium: Effective January 1, 2010, CMS revised the definition of "compendium" to include this public transparency requirement. In this revised definition, a compendium:
  - 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;
  - Is indexed by drug or biological; and
  - 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 September 15, 2021)

Medications/Drugs Covered Under Part B

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

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. Refer to the Medicare Benefit Policy Manual, Chapter 15, §110.3 – Coverage of Supplies and Accessories. (Accessed September 15, 2021)

Part B vs. Part D Guideline

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.

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 non-covered-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.

Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues. (Accessed September 15, 2021)

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 November 9, 2021)

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 non-covered 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.

Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues. (Accessed September 15, 2021)

Immunosuppressive Drugs

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

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 non-labeled 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 (Cytoxan)
- 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.

Refer to the Medicare Benefit Policy Manual, Chapter15, §50.5.1 – Immunosuppressive Drugs. (Accessed September 15, 2021)

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.

Refer to the:
- Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues. (Accessed September 15, 2021)
- Coverage Summary titled Organ and Tissue Transplants.

Hemophilia Clotting Factors

Refer to the Coverage Summary titled Blood, Blood Products and Related Procedures.

Part B vs. Part D Guideline

Hemophilia blood clotting factors would not be a Part D benefit because of the Part B coverage. Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues. (Accessed September 15, 2021)

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. Refer to the Coverage Summary titled 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.

Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues. (Accessed September 15, 2021)

Immunizations

Immunizations (e.g., pneumococcal vaccine, Hepatitis B vaccine, and influenza vaccine) are covered when criteria are met. Refer to the Coverage Summary titled 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.

Pneumococcal and influenza vaccines would not be covered under Part D because of Part B coverage.

Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues. (Accessed September 15, 2021)

Antigens/Antihistamines

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 titled 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. Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues. (Accessed September 15, 2021)

Parenteral Nutrition

Parenteral nutrition, including Intradialytic Parenteral Nutrition (IDPN), is covered under the prosthetic benefit when criteria are met. Refer to the Coverage Summary titled 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. Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues. (Accessed September 15, 2021)

Intravenous Immune Globulin (IVIG)

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
- The patient has a diagnosis of primary immune deficiency disease
  Note: For specific ICD-10-CM codes that are covered, 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. Also refer to the applicable LCDs/LCAs.
- The IVIG is administered in the home

- The treating physician has determined that administration of the IVIG in the patient's home is medically appropriate

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 September 15, 2021)

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist for IVIG and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Intravenous Immune Globulin (IVIG).

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.

Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues. (Accessed September 15, 2021)

Treatment of Autoimmune Mucocutaneous Blistering Diseases

IVIg is covered for the treatment of biopsy-proven:

- Pemphigus Vulgaris
- Pemphigus Foliaceus
- Bullous Pemphigoid
- Mucous Membrane Pemphigoid (a.k.a., Cicatricial Pemphigoid)
- Epidermolysis Bullosa Acquisita

For more specific coverage guidelines, refer to the National Coverage Determination (NCD) for Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (250.3). (Accessed September 15, 2021)

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist for IVIG and compliance with these policies is required. For specific LCDs/LCAs, refer to the table for Intravenous Immune Globulin (IVIG).

Other Indications

Medicare does not have an NCD for other indications other than the ones listed above. Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist for all states/territories and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Intravenous Immune Globulin (IVIG).

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 administer 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 Homebound.

Refer to the:

- Medicare Benefit Policy Manual Chapter 7, §50.4.3 – Covered Osteoporosis Drugs. (Accessed September 15, 2021)
- Coverage Summary titled Home Health Services, Home Health Visits, and Respite Care.

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. For more specific information, refer to the NCD for L-Dopa (160.17). (Accessed September 15, 2021) Also refer to the Outpatient L-Dopa section.

Dimethyl Sulfoxide (DMSO)

Dimethyl Sulfoxide (DMSO) is covered only when reasonable and necessary for the treatment of interstitial cystitis. Refer to the NCD for Dimethyl Sulfoxide (DMSO) (230.12). (Accessed September 15, 2021)

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. Refer to the NCD for Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (250.5).
(Accessed September 15, 2021)

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 non-hyperkeratotic 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. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50.2 – Determining Self-Administration of Drug or Biological, M-Drugs Treated as Hospital Outpatient Supplies.
(Accessed September 15, 2021)

Hereditary Angioedema (HAE) Treatment (HCPCS codes J0596, J0597, J0598 and J1290)

Medicare does not have a National Coverage Determination (NCD) for Hereditary Angioedema (HAE) treatment. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled Hereditary Angioedema (HAE), Treatment and Prophylaxis.

Note: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

Medications/Drugs Not Covered

Examples of medications/drugs that are not covered are:

Vitamin B12 Injections

Vitamin B12 injections to strengthen tendons, ligaments, etc., of the foot are not covered under Medicare because:

- There is no evidence that vitamin B12 injections are effective for the purpose of strengthening weakened tendons and ligaments, and
- This is non-surgical treatment under the subluxation exclusion.

Accordingly, Vitamin B12 injections are not considered reasonable and necessary. Refer to the NCD for Vitamin B12 Injections to Strengthen Tendons, etc., of the Foot (150.6). (Accessed September 15, 2021)

Nesiritide for Heart Failure

Nesiritide for heart failure is not covered. Refer to the NCD for Nesiritide for Treatment of Heart Failure Patients (200.1). (Accessed September 15, 2021)

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 "nitriloside" have been used interchangeably, the chemical identity of the substances to which these terms refer has varied. For more specific information, refer to the NCD for Laetrile and Related Substances (30.7). (Accessed September 15, 2021)

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. Refer to the NCD for L-Dopa (160.17) for more specific information. (Accessed September 15, 2021) Also refer to the L-Dopa section.

Investigational or Experimental Drugs

Investigational or experimental drugs are not covered. Refer to the Coverage Summary titled Experimental Procedures and Items, Investigational Devices and Clinical Trials.

Placebos

Placebos are not covered.

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.

Medications for the Treatment of Sexual Dysfunction

Medications for the treatment of sexual dysfunction including erectile dysfunction, impotence, anorgasmy, or hypoorgasmy are not covered. Refer to the Coverage Summary titled Impotence Treatment.

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. See the Coverage Summary titled Cosmetic and Reconstructive Procedures.

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. Refer to the Self-Administered Drug (SAD) Exclusion List Report. (Accessed September 15, 2021)
- 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 these drugs under the Part D Prescription Drug benefit.

Off-Label/Unlabeled Drug Use

Off-Label/unlabeled drug use is not covered unless criteria are met. Refer to the Unlabeled Use of a Part B Drug section for coverage criteria and guidelines.

Other Specific Drugs/Medications

Refer to the Other Examples of Specific Drugs/Medications table for the list of drugs/medications, applicable LCDs/LCAs, and coverage guidelines.

Review at Launch (RAL)

A pre-service organization determination is highly recommended for certain Part B medications (as defined above):

- That are new to the market;
- That have not yet undergone review by UnitedHealthcare; and
- For which a utilization management strategy has not been established.

These medications, referred to herein as RAL medications, are identified in the Other Examples of Specific Drugs/Medications table. Upon receipt of a pre-service organization determination, RAL medications will be reviewed against National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs). In the absence of an NCD, LCD or clear Medicare guidance, medical necessity reviews will be conducted using the following:

- A UnitedHealthcare Pharmacy and Therapeutics approved medical drug policy; or
- All of the following:
  - Food and Drug Administration (FDA) approved labeling, including but not limited to indication, patient age requirements, dosing recommendations, contraindications, and clinical trial inclusion criteria (ex. genetic testing, comorbid conditions); and
  - Compendia (if available); and
  - Current standard of care, as per evidenced based literature (if available)
  - Current standard of care, as per evidenced based literature (if available)

Providers are strongly encouraged to seek a pre-service organization determination for any RAL medication that has been identified in the Other Examples of Specific Drugs/Medications table. This will help to avoid gaps in coverage in the event that a prior authorization program becomes effective at a later date. If a provider believes an item or service may not be covered, or could only be covered under specific conditions, the appropriate process is to request a pre-service organization determination.

Step Therapy Program

Effective January 1, 2019, certain classes of medical benefit injectables covered under Medicare Part B will include non-preferred therapies that require prior authorization. Each class of medical injectables will include preferred therapies that do not required prior authorization. Prior authorization for a non-preferred therapy will generally require history of use of a preferred therapy within the same medical benefit injectable class, among other criteria. This prior authorization requirement will apply to some, but not all, Medicare Advantage Plans.

A medical injectable is subject to step therapy when it is listed in the Other Examples of Specific Drugs/Medications table and a notation to refer to the Medicare Part B Step Therapy Program is provided in the *Step Therapy* column.

Other Specific Medications (not listed above)

Check for available LCDs or LCAs at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. If there are no applicable LCDs or LCAs found, refer to the Outpatient Medications/Drugs and Unlabeled Use of a Part B Drug sections 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.

Shortage of Leucovorin (HCPCS code 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 (ASHP) Current Drug Shortage Bulletin. (Accessed September 15, 2021)

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

Refer to Coverage Summary titled Chemotherapy and Associated Drugs and Treatments for information on chemotherapy drugs.

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, §50.4.1 – Approved Use of Drug (Accessed September 15, 2021)

Homebound: An individual shall be considered "confined to the home" (homebound) if the following two criteria are met:

- The patient must either:
  - Because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence, or
  - Have a condition such that leaving his or her home is medically contraindicated.
- If the patient meets one of the conditions above, then the patient must also meet two additional requirements defined below.
  - There must exist a normal inability to leave home, and
  - Leaving home must require 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. Medicare Benefit Policy Manual, Chapter 15, §60.4.1 – Definition of Homebound Patient Under the Medicare Home Health (HH) Benefit (Accessed September 15, 2021)

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). Injectable drugs (including intravenous drugs) are typically eligible for inclusion under the “incident to” benefit. With limited exclusions, 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 September 15, 2021)

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 September 15, 2021)

Supporting Information

Important Note: When searching the Medicare Coverage Database, if no LCD/LCA is found, then use the applicable referenced default policy below for coverage guidelines.

Other Examples of Specific Drugs/Medications Accessed November 9, 2021 *Also refer to the MACs with corresponding States/Territories.					
Drug/Medication	NCD, Medicare Manual, LCDs/LCAs*	Default Policy for States Without LCDs/LCAs	Individual Consideration (IC)	Review at Launch (RAL)	Step Therapy
Adakveo® (crizanlizumab-tmca)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Adakveo® (Crizanlizumab-Tmca)	None	No	No
Botulinum toxin for the treatment of migraine headaches	CGS L33949 (A56472) First Coast L33274 (A57715) NGS L33646 (A52848) Noridian L35170 (A57185) L35172 (A57186) Novitas L38809 (A58423) Palmetto L33458 (A56646) WPS	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Botulinum Toxins A and B	None	No	No

Other Examples of Specific Drugs/Medications Accessed November 9, 2021 *Also refer to the MACs with corresponding States/Territories.					
Drug/Medication	NCD, Medicare Manual, LCDs/LCAs*	Default Policy for States Without LCDs/LCAs	Individual Consideration (IC)	Review at Launch (RAL)	Step Therapy
	L34635 (A57474) Note: Only use this WPS LCD/LCA if no other available Part A LCD/LCA.				
Colony stimulating factors Short acting • Granix® (tbo-filgrastim) • Neupogen® (filgrastim) • Nivestym® (filgrastim-aafi), • Zarxio® (filgrastim-sndz) Long acting • Fulphila® (pegfilgrastim-jmdb) • Neulasta® (pegfilgrastim) • Nyvepria™ (pegfilgrastim-apgf) • Udenyca® (pegfilgrastim-cbqv) • Ziextenzo® (pegfilgrastim-bmez)	First Coast L33747 (A57725) L34002 (A57789) NGS L33394 (A52408) Palmetto L37176 (A56748) (A54682)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled White Blood Cell Colony Stimulating Factors	None	No	Yes Refer to the UnitedHealthcare Medicare Advantage Medical Benefit Injectable Policy titled Medicare Part B Step Therapy Programs
Crysvita® (burosumab-twza)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Crysvita® (Burosumab-Twza)	None	No	No
Denosumab (Xgeva®, Prolia®)	CGS A58526 First Coast L33270 (A57603) NGS L33394 (A52399) (A52855) Noridian A58532, A58533 Palmetto A58527	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Denosumab (Prolia® & Xgeva®)	None	No	No

Other Examples of Specific Drugs/Medications Accessed November 9, 2021 *Also refer to the MACs with corresponding States/Territories.					
Drug/Medication	NCD, Medicare Manual, LCDs/LCAs*	Default Policy for States Without LCDs/LCAs	Individual Consideration (IC)	Review at Launch (RAL)	Step Therapy
	WPS A58544 Note: Only use this WPS LCD/LCA if no other available Part A LCD/LCA.				
Erythropoietin for Cancer Related Conditions	NCD for ESAs in Cancer and Related Neoplastic Conditions (110.21) Note: Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.	N/A	None	No	Yes Refer to the UnitedHealthcare Medicare Advantage Medical Benefit Injectable Policy titled Medicare Part B Step Therapy Programs
Erythropoietin for Non-cancer Related Conditions	CGS L34356 (A56462) First Coast L36276 (A57628) WPS L34633 (A56795) Note: Only use this WPS LCD/LCA if no other available Part A LCD/LCA.	UnitedHealthcare Commercial Medical Drug Policy titled Erythropoiesis-stimulating Agents	None	No	Yes Refer to the UnitedHealthcare Medicare Advantage Medical Benefit Injectable Policy titled Medicare Part B Step Therapy Programs
Givlaari® (givosiran)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Givlaari® (Givosiran)	None	No	No
Infliximab (Avsola™, Inflectra®, Remicade® & Renflexis®)	NGS L33394 (A52423) Palmetto	UnitedHealthcare Commercial Medical Benefit	None	No	Yes Refer to the UnitedHealthcare

Other Examples of Specific Drugs/Medications Accessed November 9, 2021 *Also refer to the MACs with corresponding States/Territories.					
Drug/Medication	NCD, Medicare Manual, LCDs/LCAs*	Default Policy for States Without LCDs/LCAs	Individual Consideration (IC)	Review at Launch (RAL)	Step Therapy
	L35677 (A56432)	Drug Policy titled Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®)			Medicare Advantage Medical Benefit Injectable Policy titled Medicare Part B Step Therapy Programs
Intravenous iron therapy for dialysis patients	NCD for Intravenous Iron Therapy (110.10)	NCD for Intravenous Iron Therapy (110.10)	None	No	No
Intravenous iron therapy for non-dialysis patients	Noridian A55653, A55734	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®)	None	No	No
Intravitreal vascular endothelial growth factor (VEGF) inhibitors • Avastin® (bevacizumab) • Lucentis® (ranibizumab) • Eylea® (aflibercept) • Beovu® (brolucizumab-dbll) • Macugen® (pegaptanib)	NGS L33394 (A52370) Novitas A53121 First Coast L36962 (A56716) Noridian A53008, A53009 Palmetto A53387	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors	None	No	Yes Refer to the UnitedHealthcare Medicare Advantage Medical Benefit Injectable Policy titled Medicare Part B Step Therapy Programs
Luxturna™ (voretigene neparvovec-rzyl)	Palmetto L37863 (A56419)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Luxturna™ (Voretigene Neparvovec-Rzyl)	None	No	No
Onpattro® (patisiran)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Onpattro® (Patisiran)	None	No	No

Other Examples of Specific Drugs/Medications Accessed November 9, 2021 *Also refer to the MACs with corresponding States/Territories.					
Drug/Medication	NCD, Medicare Manual, LCDs/LCAs*	Default Policy for States Without LCDs/LCAs	Individual Consideration (IC)	Review at Launch (RAL)	Step Therapy
Oxlumo™ (lumasiran)	None	UnitedHealthcare Commercial Medical Drug Policy for Oxlumo™ (lumasiran)	None	No	No
Primacor® (milrinone) – use in home setting Note: There are safety and efficacy issue regarding the use of Milrinone in the home setting. Read the LCDs/ LCAs before authorizing.	DME MAC LCD for External Infusion Pumps L33794	All states/territories have LCDs/LCAs	None	No	No
Radicava® (edaravone)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Radicava® (Edaravone)	None	No	No
Rituximab (Rituxan®, Ruxience®, & Truxima®) for non-chemotherapeutic indications For chemotherapeutic indications, refer to the Coverage Summary titled Chemotherapy, Associated Drugs and Treatments	CGS L38920 (A58582) NGS L33394 (A52452) Palmetto L35026 (A56380)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Rituximab (Rituxan®, Ruxience®, & Truxima®)	None	No	No
Reblozyl® (luspatercept-aamt)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Reblozyl® (Luspatercept-Aamt)	None	No	No
Ryplazim® (plasminogen, human-tvmh)	None	None	None	Refer to the Review at Launch (RAL) Guideline	No

Other Examples of Specific Drugs/Medications Accessed November 9, 2021 *Also refer to the MACs with corresponding States/Territories.					
Drug/Medication	NCD, Medicare Manual, LCDs/LCAs*	Default Policy for States Without LCDs/LCAs	Individual Consideration (IC)	Review at Launch (RAL)	Step Therapy
Saphnelo™ (anifrolumab-fnia)	None	None	None	Refer to the Review at Launch (RAL) Guideline	No
Scenesse® (afamelanotide)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Scenesse® (Afamelanotide)	None	No	No
Sodium hyaluronate injections for osteoarthritis of knee	First Coast L33767 (A57256) NGS L33394 (A52420) Novitas L35427 (A55036) WPS A56157 Note: Only use this WPS LCD/LCA if no other available Part A LCD/LCA.	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Sodium Hyaluronate	None	No	Yes Refer to the UnitedHealthcare Medicare Advantage Medical Benefit Injectable Policy titled Medicare Part B Step Therapy Programs
Soliris® (eculizumab)	NGS L33394 (A54548)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Complement Inhibitors (Soliris® & Ultomiris®)	None	No	No
Spinraza® (nusinersen)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Spinraza® (Nusinersen)	None	No	No
Tepezza® (teprotumumab-trbw)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Tepezza® (Teprotumumab-Trbw)	None	No	No

Other Examples of Specific Drugs/Medications Accessed November 9, 2021 *Also refer to the MACs with corresponding States/Territories.					
Drug/Medication	NCD, Medicare Manual, LCDs/LCAs*	Default Policy for States Without LCDs/LCAs	Individual Consideration (IC)	Review at Launch (RAL)	Step Therapy
Testopel® (testosterone pellet) (CPT code 11980 and HCPCS code J3490) Refer to the FDA Warning Letter/Notice for Testopel® (testosterone pellet).	Noridian L36569 (A57616) L36538 (A57615)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Testosterone Replacement or Supplementation Therapy	None	No	No
Ultomiris® (ravulizumab)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Complement Inhibitors (Soliris® & Ultomiris®)	None	No	No
Uplizna® (inebilizumab-cdon)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Uplizna® (Inebilizumab-Cdon)	None	No	No
Zolgensma® (onasemnogene abeparvovec-xioi)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Zolgensma® (Onasemnogene Abeparvovec-Xioi)	None	No	No

Part A and B MACs	States/Territories
CGS	KY, OH
First Coast	FL, PR, VI
NGS	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
	AS, CA, GU, HI, NV, No. Mariana Islands
Novitas	DC, AR, CO, DE, LA, MD, MS, NJ, NM, OK, PA, TX
Palmetto	AL, GA, NC, SC, TN, VA, WV
WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
DME MACs	**States/Territories**
CGS (17013)	IL, IN, KY, MI, MN, OH, WI

Part A and B MACs	States/Territories
CGS (18003)	AL, AR, CO, FL, GA, LA, MS, NC, NM, OK, PR, SC, TN, TX, VA, VI, WV
Noridian (16013)	CT, DC, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VT
Noridian (19003)	AK, AS, AZ, CA, GU, HI, IA, ID, KS, MO, MT, ND, NE, MP, NV, OR, SD, UT, WA, WY

Intravenous Immune Globulin (IVIG) Accessed November 9, 2021				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L33610 (A52509)	Intravenous Immune Globulin	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
L35891 (A56779)	Intravenous Immune Globulin	Part A and B MAC	CGS Administrators, LLC	KY, OH
L34007 (A57778)	Intravenous Immune Globulin	Part A and B MAC	First Coast Service Options, Inc.	Fl, PR, VI
L33394 (A52446)	Drugs and Biologicals, Coverage of, for Label and Off-Label Uses	Part A and B MAC	National Government Services, Inc.	CT, IL, MA, ME MN, NH, NY, RI, VT, WI
L34074 (A57194)	Immune Globulin Intravenous (IVIg)	Part A and B MAC	Noridian Healthcare Solutions, LLC	AK, ID, OR, WA AZ, MT, ND, SD, UT, WY
L34314 (A57187)	Immune Globulin Intravenous (IVIg)	Part A and B MAC	Noridian Healthcare Solutions, LLC	CA, AS, GU, HI, MP, NV
L35093 (A56786)	Intravenous Immune Globulin (IVIG)	Part A and B MAC	Novitas Solutions, Inc.	CO, NM, OK, TX, AR, LA, MS, DE, DC, MD, NJ, PA
L34580 (A56718)	Intravenous Immunoglobulin (IVIG)	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
L34771 (A57554)	Immune Globulins	Part A MAC	Wisconsin Physicians Service Insurance Corporation	AK*, AL*, AR*, AZ*, CA*, CO*, CT*, DE*, FL*, GA*, HI*, IA, ID*, IL*, IN, KS, KY*, LA*, MA*, MD*, ME*, MI, MO, MS*, MT*, NC*, ND*, NE, NH*, NJ*, NM*, NV*, OH*, OK*, OR*, PA*, RI*, SC, SD*, TN*, TX*, UT*, VA*, VT*, WA*, WI*, WV*, WY* Note: States noted with an asterisk(*) should follow the other available state-specific LCD/LCA listed in this table. This WPS LCD/LCA only applies to states without asterisk.

Intravenous Immune Globulin (IVIG) Accessed November 9, 2021				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L34771 (A57554)	Immune Globulins	Part B MAC	Wisconsin Physicians Service Insurance Corporation	IA, IN, KS, MI, MO, NE

Back to Guidelines

Policy History/Revision Information

Date	Summary of Changes

09/21/2021	**Coverage Guidelines**
	Part D Medications/Drugs
	• Revised language pertaining to "medically-accepted indication" to indicate:
	  ○ Section 1860D-2(e)(4) of the Social Security Act defines "medically-accepted indication" in part by reference to section 1927(k)(6) of the Act, to any use of a covered Part D drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act
	  ○ The recognized compendia are:
	  ▪ American Hospital Formulary Service Drug Information
	  ▪ DRUGDEX® Information System
	Immunosuppressive Drugs
	• Removed instruction on appropriate billing
	Other Examples of Specific Drugs/Medications
	Colony Stimulating Factors (Short Acting)
	• Updated list of applicable drugs/medications; added:
	  ○ Tbo-Filgrastim
	  ○ Filgrastim
	  ○ Filgrastim-Aafi
	  ○ Filgrastim-Sndz
	Colony Stimulating Factors (Long Acting)
	• Updated list of applicable drugs/medications; added:
	  ○ Pegfilgrastim-Jmdb
	  ○ Pegfilgrastim
	  ○ Pegfilgrastim-Apgf
	  ○ Pegfilgrastim-Cbqv
	  ○ Pegfilgrastim-Bmez
	Erythropoietin for Cancer Related Conditions
	• Revised language to indicate Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable
	Erythropoietin for Non-Cancer Related Conditions
	• Added instruction to refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled *Erythropoiesis-Stimulating Agents* for states with no LCDs/LCAs
	• Added step therapy requirement; refer to the UnitedHealthcare Medicare Advantage Medical Benefit Injectable Policy titled *Medicare Part B Step Therapy Programs*
	Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors
	• Updated list of applicable drugs/medications; replaced "*Compounded* Avastin® (Bevacizumab)" with "Avastin® (Bevacizumab)"
	Supporting Information
	• Updated list of available LCDs/LCAs to reflect the most current reference links

Date	Summary of Changes
	• Archived previous policy version MCS057.03

Instructions for Use

This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the Member's Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member's EOC/SB, the member's EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

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 are required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).