Medications/Drugs (Outpatient/Part B)

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➲ Instructions for Use

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Coverage Rationale

DME Face-to-Face Requirement: 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 UnitedHealthcare Medicare Advantage Medical Policy titled Durable Medical Equipment (DME), Prosthetics, Orthotics (Non-Foot Orthotics), Nutritional Therapy, and Medical Supplies Grid.

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.

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.

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.

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.

For the list of the major drug compendia for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen, refer to the Medicare Benefit Policy Manual, Chapter 15, §50.4.5.B – Recent Revision to Compendia List.

In the case of drugs used in anti-cancer chemotherapeutic regimen, refer to the Medicare Benefit Policy Manual, Chapter 15, §50.4.5 – Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen.

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**: 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; and
  - 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.

Medications/Drugs Covered Under Part B

Examples of medications/drugs that are covered under Part B include, but not limited to, the following medications/drugs.

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.

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); and
- A Medicaid-only NF that primarily furnishes skilled care; and
- 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.

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.

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); and
- A Medicaid-only NF that primarily furnishes skilled care; and
- 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.

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 Welcomes.
- 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, Chapter 15, §50.5.1 – Immunosuppressive Drugs.

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.

Hemophilia Blood Clotting Factors

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.

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.

For detailed coverage requirements, refer to the Medicare Benefit Policy Manual, Chapter 15, §50.5.3 Oral Anti-Cancer Drugs.

For claims payment and coding information, refer to the Medicare Claims Processing Manual, Chapter 17, §80.1 Oral Cancer Drugs.

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.

Note: Members may have additional coverage for oral anti-cancer under the Part D. Prescription Drug Plan, which are not covered in this medical 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.

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.

Immunizations

Immunizations (e.g., pneumococcal vaccine, Hepatitis B vaccine, and influenza vaccine) are covered when criteria are met. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50.4.4.2 – Immunizations 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.

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 Medicare Benefit Policy Manual, Chapter 15, §20.2 – Physician Expense for Allergy Treatment and §50.2 – Determining Self-Administration of Drug or Biological.

- Also refer to the:
  - Medicare Benefit Policy Manual, Chapter 15, §50.4.4.1 – Antigens.
  - Medicare Claims Processing Manual, Chapter 12, §200 – Allergy Testing and Immunotherapy.
- 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/search.aspx.

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.

Parenteral Nutrition

Parenteral nutrition, including Intradialytic Parenteral Nutrition (IDPN), is covered under the prosthetic benefit when criteria are met. Refer to the UnitedHealthcare Medicare Advantage Medical Policy titled Durable Medical Equipment (DME), Prosthetics, Orthotics (Non-Foot Orthotics), Nutritional Therapy, and Medical Supplies Grid 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.

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.

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.

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).

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 8 – Covered Osteoporosis Drugs
- UnitedHealthcare Medicare Advantage Medical Policy titled Home Health Services, Home Health Visits, Respite Care, and Hospice Care

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.

Medications/Drugs Not Covered

Examples of medications/drugs that are not covered are listed below.

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, Ligaments, etc., of the Foot (150.6).

Investigational or Experimental Drugs

Investigational or experimental drugs are not covered. Refer to the Medical Benefit Policy Manual, Chapter 15, §50.4.3 – Examples of Not Reasonable and Necessary.

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.

Erectile dysfunction (ED) drugs will meet the definition of a Part D drug when prescribed for medically accepted indications approved by the FDA other than sexual or erectile dysfunction (such as pulmonary hypertension). However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX® Information System.

Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1 – Excluded Categories.

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. Refer to the UnitedHealthcare Medicare Advantage Medical Policy 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 Medicare Coverage Database.
- **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.

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; and
- 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).

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

Certain classes of medical benefit injectables covered under Medicare Part B will include preferred and non-preferred therapies. Non-preferred therapies will generally require history of use of a preferred therapy among other criteria. This step therapy 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 UnitedHealthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs is provided in the Step Therapy column.

Maximum Dosage and Frequency

Provides information about the maximum dosage per administration and dosing frequency for certain medications Administered by a medical professional. Most medications have a maximum dosage and frequency based upon body surface area or patient weight or a set maximal dosage and frequency independent of patient body size.

A medication is subject to maximum dosage and frequency when it is listed in the Other Examples of Specific Drugs/Medications table and a notation to refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency is provided in the Maximum Dosage and Frequency column.

Note: Any LCD/LCA maximum dosage and frequency criteria would be applicable, if available.

Other Specific Medications (Not Listed Above)

For Oncology Medications

- Check for available NCDs, LCDs or LCAs at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. If there are no applicable NCDs, LCDs or LCAs found, refer to Supporting Information table within this Medical Policy.
- Also refer to the Medicare Benefit Policy Manual, Chapter 15, §50.4 Reasonableness and Necessity. For any off label drug or biological with a NCCN Category 2B indication refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage.

For Non-Oncologic Medications

- Check for available NCDs, LCDs or LCAs at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. If there are no applicable NCDs, LCDs or LCAs found, refer to Supporting Information table within this Medical Policy.

- For all other drugs or biologicals (non-oncologic) not listed in this Medical Policy, for which there are no applicable NCDs, LCDs or LCAs, refer to the relevant UnitedHealthcare Commercial Medical Benefit Drug Policy. If there is no UnitedHealthcare Commercial Drug Policy, then use the compendia and evidence-based medical literature for coverage guidance. For available UnitedHealthcare Commercial Medical Benefit Drug Policies, refer to https://www.uhcprovider.com/en/policies-protocols/commercial-policies/commercial-medical-drug-policies.html.

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.

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.

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.

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.

Supporting Information

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Adakveo® (crizanlizumab-tmca)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Adakveo® (Crizanlizumab-Tmca)	No	No	No
Adzynma (ADAMTS13, recombinant-krhn)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Adzynma (ADAMTS13, Recombinant-Krhn)	No	No	No
Amvuttra™ (vutrisiran)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled RNA-Targeted Therapies (Amvuttra® and Onpattro®)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Antiemetics (oral) for Oncology - Neurokinin 1 Receptor Antagonist (NK1 RA), 5-hydroxytrypta-mine Receptor Antagonist (5HT3 RA), NK1 RA/5HT3 RA combination • Akynzeo® (netupitant and palono-setron) capsule • Emend® (aprepitant) capsule • Kytril® (granisetron) tablets • Varubi® (rolapitant) tablet • Zuplenz, Zofran ODT®, Zofran® (ondanset-ron) tablets	Medicare Benefit Policy Manual, Chapter 15, §50.5.4 – Oral Anti-Nausea (Anti Emetic) Drugs DME MAC L33827	N/A	No	No	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Antiemetics (injectable) for Oncology - Neurokinin 1 Receptor Antagonist (NK1 RA), 5-hydroxytrypta-mine Receptor Antagonist (5HT3 RA), NK1 RA/5HT3 RA combination • Akynzeo® (netupitant and palonosetron) injection • Aloxi® (palonosetron hydrochlor-ide) injection • Cinvanti® (aprepitant) injectable emulsion • Emend® (fosaprepitan) injection • Kytril® (granisetron) injection • Sustol® (granisetron) injection • Zuplenz, Zofran ODT®, and Zofran® (ondansetron) injection	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Antiemetics for Oncology	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
Antineoplastic Monoclonal Antibodies • Keytruda® (pembrolizumab) • Libtayo® (cemiplimab-rwlc) • Loqtorzi™ (toripalimab-tpzi) • Opdivo® (nivolumab) • Tecentriq® (atezolizumab) • Yervoy® (nivolumab)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Asthma Immunomodulators • Cinqair® (reslizumab) • Fasenra® (benralizumab) • Nucala® (mepolizumab)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Beqvez (fidanacogene elaparvovec-dzkt)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Gene Therapies for Hemophilia B	No	No	No
Bevacizumab • Alymsys® (bevacizumab-maly) • Avastin® (bevacizu-mab) • Avzivi® (bevacizumab-tnjn) • Mvasi® (bevacizumab-Awwb) • Vegzelma® (bevacizumab-adcd) • Zirabev® (bevacizumab-bvzr) – Oncology Use Only	**NGS** L33394 (A52370)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Botulinum toxin • Botox® (onabotulinum-toxinA) • Daxxify® (daxibotulinum-toxinA-lanm) • Dysport® (abobotulinum-toxinA) • Myobloc® (rimabotulinum-toxinB) • Xeomin® (incobotulinum-toxinA)	**CGS** L33949 (A56472) **First Coast** L33274 (A57715) **NGS** L33646 (A52848) **Noridian** L35170 (A57185) L35172 (A57186) **Novitas**** L38809 (A58423) **Palmetto**** L33458 (A56646)	All states/territories have LCDs/LCAs	No	No	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
	WPS* L34635 (A57474) **Note**: Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable	All states/territories have LCDs/LCAs	No	No	No
Briumvi™ (ublituximab-xiiy)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Briumvi® (Ublituximab-Xiiy)	No	No	No
CAR-T Cellular Therapy • Abecma® (idecaptagene cicleucel) • Breyanzi® (lisocabtagene maraluecel) • Carvykti™ (ciltacabtagene autoleucel) • Kymriah® (tisagenlecleucel) • Tecartus® (brexucabtagene autoleucel) • Yescarta® (axicabtagene ciloleucel)	None	Optum Clinical Guidelines titled Chimeric Antigen Receptor T-cell T (CAR T) Therapy	No	No	No
Cellular Therapy • Amtagvi™ (lifeucel) • Tecelra® (afamitresgene autoleucel)	None	Optum Clinical Guidelines titled Tumor-Infiltrating Lymphocyte (TIL) Cell Therapy Optum Clinical Guidelines titled T-Cell Receptor T-Cell (TCR T) Therapy	No	No	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Colony stimulating factors **Short acting** • Granix® (tbo-filgrastim) • Neupogen® (filgrastim) • Nivestym® (filgrastim-aafi) • Nypozi (filgrastim-txid) • Releuko® (filgrastim-ayow) • Zarxio® (filgrastim-sndz) **Long acting** • Fulphila® (pegfilgrastim-jmdb) • Fylnetra® (pegfilgrastim-pbbk) • Neulasta® (pegfilgrastim) • Nyvepria™ (pegfilgrastim-apgf) • Rolvedon™ (eflapegrastim-xnst) • Stimufend® (pegfilgrastim-fpgk) • Udenyca® (pegfilgrastim-cbqv) • Ziextenzo® (pegfilgrastim-bmez)	**Palmetto**** L37176 (A56748) (A54682)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled White Blood Cell Colony Stimulating Factors	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Cosentyx® IV (secukinumab)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Cosentyx® (Secukinumab)	No	No	No
Crysvita® (burosumab-twza)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Crysvita® (Burosumab-Twza)	No	No	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Denosumab • Xgeva® • Prolia®	**NGS** L33394 (A52399) (A52855)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Denosumab (Prolia® & Xgeva®)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Denosumab-bbdz • Jubbonti® • Wyost®	None	N/A	**Yes** Refer to Review at Launch (RAL)	No	No
Elevidys® (delandistrogene moxeparvovec-rokl)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Elevidys™ (Delandistrogene Moxparvovec-Rokl)	No	No	No
Enjaymo® (sutimlimab-jome)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Enjaymo® (Sutimlimab-Jome)	No	No	No
Evenity® (Romosozumab-Aqqg)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Evenity® (Romosozumab-Aqqg)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
Entyvio® (vedolizumab)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Entyvio® (Vedolizumab)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Entyvio® (vedolizumab)	Entyvio® (vedolizumab)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Entyvio® (Vedolizumab)	No	No	Dosage and Frequency
Erythropoietin for Cancer Related Conditions	NCD for Erythropoiesis Stimulating Agents (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.	N/A	No	No	No
Erythropoietin for Non-cancer Related Conditions	**CGS** L34356 (A56462) **Palmetto**** L39237 (A58982) **WPS*** L34633 (A56795)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Erythropoiesis-Stimulating Agents	No	No	No
Evkeeza® (Evinacumab-Dgnb)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Evkeeza® (Evinacumab-Dgnb)	No	No	No
Gemcitabine Infugem™ (gemcitabine)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
Gene Therapy (ex vivo) • Casgevy® (exagamglogene autotemcel) • Lenmeldy™ (atidarsagene autotemcel)	None	Optum Clinical Guidelines titled Gene Therapy	No	No	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
• Lyfgenia™ (lovotibeglogene autotemcel) • Skysona® (elivaldogene autotemcel) • Zynteglo® (betibeglogene autotemcel)	None	Optum Clinical Guidelines titled Gene Therapy	No	No	No
Givlaari® (givosiran)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Givlaari® (Givosiran)	No	No	No
Gonadotropin Releasing Hormone Analogs • Leuprolide Acetate	**NGS** L33394 (A52453)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Gonadotropin Releasing Hormone Analogs	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
Hemgenix® (etranacogene dezaparvovec-drlb)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Gene Therapies for Hemophilia B	No	No	No
Hympavzi™ (marstacimab-hncq)	None	N/A	**Yes** Refer to Review at Launch (RAL)	No	No
Infliximab • Avsola® (infliximab-axxq) • Inflectra® (infliximab-dyyb) • Infliximab • Remicade® (infliximab) • Renflexis® (infliximab-abda)	**NGS** L33394 (A52423) **Palmetto**** L35677 (A56432)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Infliximab (Avsola®, Inflectra®, Remicade®, & Renflexis®)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Intravenous Immune Globulin (IVIG)	Refer to the Intravenous Immune Globulin (IVIG) table	N/A	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
Intravenous iron therapy for **dialysis patients**	NCD for Intravenous Iron Therapy (110.10)	N/A	No	No	No
Intravenous iron therapy for **non-dialysis patients**	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
Intravitreal vascular endothelial growth factor (VEGF) inhibitors • Cimerli® (ranibizumab-eqrn) • Compounded Avastin® (bevacizu-mab) • Lucentis® (ranibizumab) • Eylea® (aflibercept) • Eylea® HD (aflibercept) • Beovu® (brolucizumab-dbll) • Byooviz® (ranibizumab-nuna) • Susvimo® (ranibizumab injection) • Vabysmo® (faricimab-svoa)	**NGS** L33394 (A52370, A52451) **Noridian** A53008, A53009 **Palmetto**** A53387	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Izervay™ (avacincaptad pegol intravitreal solution)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Ophthalmologic Complement Inhibitors	No	No	No
Krystexxa® (Pegloticase)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Krystexxa® (Pegloticase)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Lantidra™ (donislecel)	None	Optum Clinical Guidelines titled Solid Organ Transplantation	No	No	No
Leqvio® (inclisiran)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Leqvio® (Inclisiran)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Leucovorin/ Levoleucovorin • Fusilev® (levoleuco-vorin) • Khapzory™ (levoleuco-vorin)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
Luxturna® (voretigene neparvovec-rzyl) Luxturna® (voretigene neparvovec-rzyl)	**Palmetto**** L37863 (A56419)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Luxturna® (Voretigene Neparvovec-Rzyl)	No	No	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease • Aduhelm® (aducanumab-avwa) • Kisunla™ (donanemab-azbt) • Leqembi® (lecanemab)	NCD for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (200.3) For payment rules for NCDs requiring CED, refer to the Medicare Managed Care Manual, Chapter 4, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)	N/A	No	No	No
Ocrevus® (ocrelizumab)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq)	None	N/A	**Yes** Refer to Review at Launch (RAL)	No	No
Omvoh™ (mirikizumab-mrkz)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Omvoh™ (Mirikizumab-Mrkz)	No	No	No
Onpattro® (patisiran)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled RNA-Targeted Therapies (Amvuttra® and Onpattro®)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Orencia® (abatacept)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Orencia® (Abatacept) Injection for Intravenous Infusion	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Oxlumo® (lumasiran)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oxlumo® (Lumasiran) and Rivfloza™ (Nedosiran)	No	No	No
Pavblu™ (aflibercept-ayyh)	None	N/A	**Yes** Refer to Review at Launch (RAL)	No	No
Pemetrexed • Alimta® (pemetrexed) • Pemetrexed • Pemfexy® (pemetrexed) • Pemrydi RTU® (pemetrexed)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
PiaSky® (crovalimab-akkz)	None	N/A	**Yes** Refer to Review at Launch (RAL)	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	No	No	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Qalsody® (tofersen)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Qalsody® (Tofersen)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Radicava® (edaravone)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Radicava® (Edaravone)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Rituximab • Riabni® (rituximab-aarx) • Rituxan® (rituximab) • Ruxience® (rituximab-pvvr) • Truxima® (rituximab-abbs) **for non-chemo-therapeutic indications**	**CGS** L38920 (A58582) L38268 (A57160) **NGS** L39297 (A59101) **Palmetto**** L35026 (A56380) **WPS*** A55639	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Rituximab • Riabni® (rituximab-aarx) • Rituxan® (rituximab) • Rituxan Hycela® **(rituximab and hyaluronic-dase)** • Ruxience®(rituximab-pvvr) • Truxima® (rituximab-abbs) **for chemo-therapeutic indications**	**NGS** L39297 (A59101) **Palmetto**** L35026 (A56380)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Rivfloza® (nedosiran)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oxlumo® (Lumasiran) and Rivfloza™ (Nedosiran)	No	No	No
Reblozyl® (luspatercept-aamt)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Reblozyl® (Luspatercept-Aamt)	No	No	No
Roctavian™ (valoctocogene roxaparvovec-rvox)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Roctavian™ (Valoctocogene Roxaparvovec-Rvox)	No	No	No
Ryplazim® (plasminogen, human-tvmh)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Ryplazim® (Plasminogen, Human-Tvmh)	No	No	No
Rystiggo® (rozanolixizumab-noli)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Neonatal Fc Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Saphnelo® (anifrolumab-fnia)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Saphnelo® (Anifrolumab-Fnia)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Skyrizi® (Risankizumab-rzaa)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Skyrizi® (Risankizumab-Rzaa)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Sodium hyaluronate injections **for osteoarthritis of knee**	**NGS** L33394 (A52420) **Palmetto**** L39260 (A59030) **WPS*** L39529	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Sodium Hyaluronate	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
Soliris® (eculizumab)	**NGS** L33394 (A54548)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Complement Inhibitors (PiaSky®, Soliris®, & Ultomiris®)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Spevigo® (spesolimab-sbzo)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Spevigo® (Spesolimab-Sbzo)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Spinraza® (nusinersen)	**Noridian** A58578, A58579	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Spinraza® (Nusinersen)	No	No	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Subcutaneous Immune Globulin (SCIG)	**First Coast** L34007 (A57778) **Novitas**** L35093 (A56786) **WPS*** L34771 (A57554) **CGS*** (DME MAC)** L33794 (A52507) **Noridian*** (DME MAC)** L33794 (A52507)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Immune Globulin (IVIG and SCIG)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	No
Syfovre® (pegcetacoplan injection)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Ophthalmologic Complement Inhibitors	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Tepezza® (teprotumumab-trbw)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Tepezza® (Teprotumumab-Trbw)	No	No	No
Teplizumab • Tzield® (teplizumab-mzwv)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Tzield® (Teplizumab-Mzwv)	No	No	No
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) **Palmetto**** L39086 (A58828)	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Testosterone Replacement or Supplementation Therapy	No	No	No

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Tezspire® (tezepelumab-ekko)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Tezspire® (Tezepelumab-Ekko)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Tocilizumab • Actemra® (tocilizumab) • Tofidence™ (tocilizumab-bavi) • Tyenne® (tocilizumab-aazg)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Actemra® (Tocilizumab) Injection for Intravenous	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Trastuzumab • Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk) • Herceptin® (trastuzumab) • Hercessi™ (trastuzumab-strf) • Herzuma® (trastuzumab-pkrb) • Kanjinti® (trastuzumab-anns) • Ogivri® (trastuzumab-dkst) • Ontruzant® (trastuzumab-dttb) • Trazimera® (trastuzumab-qyyp)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Ultomiris® (ravulizumab)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Complement Inhibitors (PiaSky®, Soliris®, & Ultomiris®)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Uplizna® (inebilizumab-cdon)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Uplizna® (Inebilizumab-Cdon)	No	No	No
Vyjuvek® (beremagene geperpavec-svdt)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Vyjuvek® (Beramagene Geperpavec-Svdt)	No	No	No
Vyepti® (Eptinezumab- Jjmr)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Vyepti® (Eptinezumab-Jjmr)	No	**Yes** Refer to the United-Healthcare Medicare Advantage Drug Policy titled Medicare Part B Step Therapy Programs	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Vyvgart® (efgartigimod)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Neonatal Fc Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency

Other Examples of Specific Drugs/Medications *Also refer to the MACs With Corresponding States/Territories.					
Drug/ Medication	**NCD, Medicare Manual, LCDs/LCAs***	**Default Policy for States Without LCDs/LCAs**	**Review at Launch (RAL)**	**Step Therapy**	**Maximum Dosage and Frequency***
Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Neonatal Fc Receptor Blockers (Rystiggo®, Vyvgart®, & Vyvgart® Hytrulo)	No	No	**Yes** Refer to the United-Healthcare Commercial Medical Benefit Drug Policy titled Maximum Dosage and Frequency
Yimmugo® (immune globulin intravenous, human – dira)	Refer to the Intravenous Immune Globulin (IVIG) table	N/A	**Yes** Refer to Review at Launch (RAL)	No	No
Zolgensma® (onasemnogene abeparvovec-xioi)	None	UnitedHealthcare Commercial Medical Benefit Drug Policy titled Zolgensma® (Onasemnogene Abeparvovec-Xioi)	No	No	No
Back to Guidelines					

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	LCA	Contractor Type	Contractor Name
Intravenous Immune Globulin (IVIG)				
N/A	L35891 Intravenous Immune Globulin	A56779 Billing and Coding: Intravenous Immune Globulin	Part A and B MAC	CGS
	L34007 Immune Globulin	A57778 Billing and Coding: Immune Globulin	Part A and B MAC	First Coast
	L39314 Off-Label Use of Intravenous Immune Globulin (IVIG)	A59105 Billing and Coding: Off-Label Use of Intravenous Immune Globulin (IVIG)	Part A and B MAC	NGS
	L34074 Immune Globulin Intravenous (IVIg)	A57194 Billing and Coding: Immune Globulin Intravenous (IVIg)	Part A and B MAC	Noridian
	L34314 Immune Globulin Intravenous (IVIg)	A57187 Billing and Coding: Immune Globulin Intravenous (IVIg)	Part A and B MAC	Noridian
	L35093 Immune Globulin	A56786 Billing and Coding: Immune Globulin	Part A and B MAC	Novitas**

NCD	LCD	LCA	Contractor Type	Contractor Name
Intravenous Immune Globulin (IVIG)				
N/A	L34580 Intravenous Immunoglobulin (IVIG)	A56718 Billing and Coding: Intravenous Immunoglobulin (IVIG)	Part A and B MAC	Palmetto**
	L34771 Immune Globulins	A57554 Billing and Coding: Immune Globulins	Part A and B MAC	WPS*
	L33610 Intravenous Immune Globulin	A52509 Intravenous Immune Globulin - Policy Article	DME MAC	Noridian*** (16013)
				CGS*** (18003)
				Noridian*** (19003)
				CGS*** (17013)

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)***	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)***	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
Notes	
*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers. **For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction. ***For DME MAC states/territories, refer to the DME MAC table below.	

Durable Medical Equipment (DME) Medicare Administrative Contractors (MAC) with Corresponding States/Territories	
DME MAC Name (Abbreviation)	**States/Territories**
CGS (17013)	IL, IN, KY, MI, MN, OH, WI
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, MP, MT, ND, NE, NV, OR, SD, UT, WA, WY

CMS Benefit Policy Manual

Medicare Benefit Policy Manual Chapter 7, §50.4.3 8 – Covered Osteoporosis Drugs
Medicare Benefit Policy Manual, Chapter 15, §20.2 – Physician Expense for Allergy Treatment
Medicare Benefit Policy Manual, Chapter 15, §50 – Drugs and Biologicals
Medicare Benefit Policy Manual, Chapter 15, §50.2 – Determining Self-Administration of Drug or Biological
Medicare Benefit Policy Manual, Chapter 15, §50.4.1 – Approved Use of Drug
Medicare Benefit Policy Manual, Chapter 15, §50.4.2 – Unlabeled Use of Drug
Medicare Benefit Policy Manual, Chapter 15, §50.4 Reasonableness and Necessity
Medicare Benefit Policy Manual, Chapter 15, §50.4.3 – Examples of Not Reasonable and Necessary
Medicare Benefit Policy Manual, Chapter 15, §50.4.4.1 – Antigens

Medicare Benefit Policy Manual, Chapter 15, §50.4.4.2 – Immunizations
Medicare Benefit Policy Manual, Chapter 15, §50.4.5 – Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen
Medicare Benefit Policy Manual, Chapter 15, §50.4.5.B – Recent Revision to Compendia List
Medicare Benefit Policy Manual, Chapter 15, §50.5.1 – Immunosuppressive Drugs
Medicare Benefit Policy Manual, Chapter 15, §50.5.3 Oral Anti-Cancer Drugs
Medicare Benefit Policy Manual, Chapter 15, §50.5.4 – Oral Anti-Nausea (Anti Emetic) Drugs
Medicare Benefit Policy Manual, Chapter 15, §50.6 – Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home
Medicare Benefit Policy Manual, Chapter 15, §60.4.1 – Definition of Homebound Patient Under the Medicare Home Health (HH) Benefit
Medicare Benefit Policy Manual, Chapter 15, §110.3 – Coverage of Supplies and Accessories

CMS Claims Processing Manual

Medicare Claims Processing Manual, Chapter 12, §200 – Allergy Testing and Immunotherapy
Medicare Claims Processing Manual, Chapter 17, §80.1 Oral Cancer Drugs

CMS Prescription Drug Benefit Manual

Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues
Medicare Prescription Drug Benefit Manual, Chapter 6, §10 – Definition of Part D Drugs
Medicare Prescription Drug Benefit Manual Chapter 6, §10.6 – Medically Accepted Indication
Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1 – Excluded Categories

Policy History/Revision Information

Date	Summary of Changes

01/01/2025	**Template Update**
	• Reformatted and reorganized policy; transferred content to new template
	• Changed policy type classification from “Coverage Summary” to “Medical Policy”
	• Updated *Instructions for Use*
	Related Policies
	• Added reference link to the:
	  ○ UnitedHealthcare Medicare Advantage Medical Policy titled *Treatment of Temporomandibular Joint (TMJ)*
	  ○ Optum Clinical Guideline titled:
	  ▪ *Chimeric Antigen Receptor T-cell (CAR T) Therapy*
	  ▪ *Gene Therapy*
	  ▪ *Solid Organ Transplantation*
	  ▪ *T-Cell Receptor T-Cell (TCR T) Therapy*
	  ▪ *Tumor-Infiltrating Lymphocyte (TIL) Cell Therapy*
	• Removed reference link to the UnitedHealthcare Medicare Advantage Policy Guideline titled *Immune Globulin*
	Coverage Rationale
	• Removed content/language addressing:
	  ○ Dermal injections for the treatment of facial lipodystrophy syndrome (LDS) (HCPCS code Q2026) (refer to the Medicare Coverage Database for applicable coverage guidelines)
	  ○ Drugs for chelation therapy for the treatment of heavy metal toxicity and non-overload conditions
	  ○ Hereditary angioedema (HAE) treatment (HCPCS codes J0596, J0597, J0598, and J1290)
	• Removed language indicating the guidelines in this Medicare Advantage Coverage Summary are for specific procedures/medications only; for procedures/medications not addressed in this Medicare Advantage Coverage Summary, refer to the Medicare Coverage Database to search for applicable coverage policies [National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs)]
	Part B vs. Part D Guideline
	Immunosuppressive Drugs

Date	Summary of Changes
	• Replaced reference to "*Agma* (antithymocyte globulin), Upjohn" with "*Atgam* (antithymocyte globulin), Upjohn" ***Other Examples of Specific Drugs/Medications*** • Added coverage guidelines for: ○ **Antineoplastic monoclonal antibodies** [Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Loqtorzi™ (toripalimab-tpzi), Opdivo® (nivolumab), Tecentriq® (atezolizumab), and Yervoy® (nivolumab)]; added language to indicate: ▪ For states without LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled *Oncology Medication Clinical Coverage* ▪ Step therapy is required; refer to the UnitedHealthcare Medicare Advantage Drug Policy titled *Medicare Part B Step Therapy Programs* ○ **Asthma immunomodulators** [Cinqair® (reslizumab), Fasenra® (benralizumab), and Nucala® (mepolizumab)]; added language to indicate: ▪ For states without LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled *Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)* ▪ Step therapy is required; refer to the UnitedHealthcare Medicare Advantage Drug Policy titled *Medicare Part B Step Therapy Programs* ▪ This medication is subject to maximum dosage and frequency guidelines; refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled *Maximum Dosage and Frequency* ○ **Hympavzi™ (marstacimab-hncq)**; added language to indicate a pre-service review [Review at Launch (RAL)] is required ○ **Pemetrexed** [Alimta® (pemetrexed), Pemetrexed, Pemfexy® (pemetrexed), and Pemrydi RTU® (pemetrexed)]; added language to indicate: ▪ For states without LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled *Oncology Medication Clinical Coverage* ▪ Step therapy is required; refer to the UnitedHealthcare Medicare Advantage Drug Policy titled *Medicare Part B Step Therapy Programs* ○ **Tocilizumab** [Actemra® (tocilizumab), Tofidence™ (tocilizumab-bavi), and Tyenne® (tocilizumab-aazg)]; added language to indicate: ▪ For states without LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled *Actemra® (Tocilizumab) Injection for Intravenous* ▪ Step therapy is required; refer to the UnitedHealthcare Medicare Advantage Drug Policy titled *Medicare Part B Step Therapy Programs* ▪ This medication is subject to maximum dosage and frequency guidelines; refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled *Maximum Dosage and Frequency* • Updated list of applicable drugs/medications for: ○ Bevacizumab; added Avzivi® (bevacizumab-tnjn) ○ Cellular therapy; added Tecelra® (afamitresgene autoleucel) ○ Colony stimulating factors (short acting); added Nypozi (filgrastim-txid) ○ Infliximab; removed Zymfentra™ (infliximab-dyyb) ○ Trastuzumab; added Hercessi™ (trastuzumab-strf) • Revised coverage guidelines for **cellular therapy**; added instruction to refer to the Optum Clinical Guidelines titled *T-Cell Receptor T-Cell (TCR T) Therapy* for states without LCDs/LCAs **Centers for Medicare & Medicaid (CMS) Related Documents** • Updated list of documents available in the *Medicare Coverage Database* to reflect the most current information • Added notation to indicate: ○ For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction ○ For Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) states/territories, refer to the DME MAC table [listed in the policy] • Added reference link to the: ○ CMS *Medicare Benefit Policy Manual*: ▪ *Chapter 7, §50.4.3 8 – Covered Osteoporosis Drugs* ▪ *Chapter 15, §20.2 – Physician Expense for Allergy Treatment*

Date	Summary of Changes
	▪ *Chapter 15, §50 – Drugs and Biologicals* ▪ *Chapter 15, §50.2 – Determining Self-Administration of Drug or Biological* ▪ *Chapter 15, §50.4.1 – Approved Use of Drug* ▪ *Chapter 15, §50.4.2 – Unlabeled Use of Drug* ▪ *Chapter 15, §50.4 Reasonableness and Necessity* ▪ *Chapter 15, §50.4.3 – Examples of Not Reasonable and Necessary* ▪ *Chapter 15, §50.4.4.1 – Antigens* ▪ *Chapter 15, §50.4.4.2 – Immunizations* ▪ *Chapter 15, §50.4.5 – Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen* ▪ *Chapter 15, §50.4.5.B – Recent Revision to Compendia List* ▪ *Chapter 15, §50.5.1 – Immunosuppressive Drugs* ▪ *Chapter 15, §50.5.3 Oral Anti-Cancer Drugs* ▪ *Chapter 15, §50.5.4 – Oral Anti-Nausea (Anti Emetic) Drugs* ▪ *Chapter 15, §50.6 – Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home* ▪ *Chapter 15, §60.4.1 – Definition of Homebound Patient Under the Medicare Home Health (HH) Benefit* ▪ *Chapter 15, §110.3 – Coverage of Supplies and Accessories* ○ CMS *Medicare Claims Processing Manual*: ▪ *Chapter 12, §200 – Allergy Testing and Immunotherapy* ▪ *Chapter 17, §80.1 Oral Cancer Drugs* ○ CMS *Medicare Prescription Drug Benefit Manual*: ▪ *Chapter 6, Appendix C – Medicare Part B versus Part D Coverage Issues* ▪ *Chapter 6, §10 – Definition of Part D Drugs* ▪ *Chapter 6, §10.6 – Medically Accepted Indication* ▪ *Chapter 6, Section 20.1 – Excluded Categories* **Supporting Information** • Archived previous policy version MCS057.35

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference 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. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be

accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.