Oscar Clinical Guideline: Quantity Limit Exception Criteria (PG200, Ver. 4)

Quantity Limit Exception Criteria

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

This policy applies to all prescription medications with quantity limits for members enrolled in the Plan's pharmacy and/or medical benefit. The purpose of this policy is to establish evidence-based criteria for prior authorization of medication quantities exceeding the Plan's limits and/or established Plan Clinical Guidelines. The goal is to ensure appropriate utilization of medications based on FDA-approved dosing, nationally recognized compendia, clinical practice guidelines, and peer-reviewed medical literature while promoting safe, effective, and cost-effective use of prescription drugs.

The Plan has established quantity limits for certain products, drugs, and biologicals to restrict the amount of medication that can be dispensed during a specific time period. These limits are designed to promote adherence to recommended dosing schedules, and prevent stockpiling or diversion of medications. However, the Plan recognizes that, in some cases, members may require higher quantities of medication due to individual clinical circumstances, such as variations in weight, metabolism, disease severity, or treatment response.

Requests for quantity limit exceptions will be evaluated on a case-by-case basis, taking into account factors such as the member's diagnosis, prescribed dosage regimen, previous treatment history, and the prescriber's clinical rationale for exceeding the established limit. The Plan will also consider the available evidence from FDA-approved labeling, nationally recognized compendia, clinical practice guidelines, and peer-reviewed literature to support the decision. Special considerations will be given to requests involving off-label use, dose optimization during medication initiation or titration, or use in specific patient populations to ensure the requested quantity is appropriate and medically necessary.

NOTE: If the requested medication requires a drug-specific prior authorization in addition to a quantity limit exception, the drug-specific prior authorization must be requested and approved before the quantity limit exception request can be considered. The approval of a quantity limit exception does not override the need for any other applicable prior authorization requirements.

Definitions

"Clinical Practice Guidelines" are evidence-based recommendations developed by expert panels or professional associations to guide healthcare providers in making decisions about appropriate diagnostic, therapeutic, or preventive interventions for specific clinical circumstances.

"Compendia" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Elsevier Clinical Pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"Evidence-based, peer-reviewed medical journals" are publications that publish original research and scholarly articles related to the medical field. These journals use a peer-review process in which submitted articles are reviewed by independent experts in the same field to ensure their scientific accuracy, validity, and reliability before publication. The articles published in these journals are often based on research that use rigorous scientific methods to provide evidence for medical practices, therapies, and treatments. The goal of evidence-based medicine is to provide the most effective care to patients based on the best available scientific evidence.

"FDA," or the Food and Drug Administration, is an agency of the United States federal government responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, and veterinary products. The FDA's main goal is to ensure that these products are safe and effective for their intended use, and that their labeling and marketing are truthful and not misleading.

"FDA-approved Labeling" is the official description of a drug product, including its intended uses, dosage, route of administration, and other information, as approved by the U.S. Food and Drug Administration (FDA).

"Medical Necessity" refers to healthcare services or supplies that are determined by the plan to be necessary, appropriate, and consistent with generally accepted standards of care for the diagnosis, treatment, or prevention of a medical condition.

"Off-label" refers to a diagnosis, condition, age group, dose, frequency, dosage form (e.g., oral tablet, solution, capsules), duration, site or route of administration, or other factor related to prescribing, for which a product (e.g., prescription drug or over-the-counter product) has not been explicitly approved or cleared by the FDA.

"Quantity Limit" refers to a restriction on the amount or quantity of medication that can be dispensed during a specific time period.

"Quantity Limit Exception" is a request to dispense a medication at a quantity or dosage that exceeds the plan's established quantity limit for a given time period.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Quantities Exceeding Established Plan Limits

The Plan considers medication quantities exceeding established Plan limits medically necessary when ALL of the following criteria are met:

1. The member has a documented diagnosis for the requested medication that is supported by ONE (1) of the following:
    a. FDA-approved labeling*; or*
    b. Nationally recognized compendia (e.g., American Hospital Formulary Service Drug Information, American Medical Association, Clinical Pharmacology, Micromedex DrugDex, National Comprehensive Cancer Network Drugs and Biologics Compendium, United States Pharmacopeia-National Formulary [USP-NF])*; or*
    c. Clinical practice guidelines from nationally recognized professional associations or governmental agencies; *or*
    d. Peer-reviewed medical literature from a major scientific or medical publication; *AND*
2. The prescribed age, dose, frequency, and duration of therapy are consistent with ONE (1) of the following:
    a. FDA-approved labeling; *or*
    b. Nationally recognized compendia; *or*
    c. Clinical practice guidelines from nationally recognized professional associations or governmental agencies; *or*
    d. Peer-reviewed medical literature from a major scientific or medical publication; *AND*
3. The prescribed dosage (i.e., dose and/or frequency) cannot be achieved using a different dose, dosage form, or strength that is covered within the Plan's limits; *AND*
4. The prescriber provides compelling clinical rationale for exceeding the established quantity limit that is supported by at least ONE (1) of the following:
    a. The member has tried and failed an adequate trial (e.g. ≥ 3 months or as applicable based on the medication and indication) of the medication at the Plan's quantity limit, as evidenced by paid claims, pharmacy records, or chart notes; *or*
    b. The member requires a higher dose due to well-documented clinical circumstances[⁂], such as variations in weight, metabolism (e.g., pharmacogenetic variations), absorption, body size, or disease severity that necessitate doses beyond the established limit per recognized treatment guidelines; *or*

        [⁂]*e.g., for topical products, the requested quantity is needed for treatment of a larger affected surface area.*
    c. The member has a diagnosis that requires a higher FDA-approved or compendia-supported dose or longer duration of therapy than accommodated by the Plan's quantity limit; *AND (if applicable)*

Additional Considerations (i.e., Additional Criteria for Special Circumstances):

5. For requests exceeding the FDA-approved dosing, frequency or duration of therapy, the prescriber provides additional clinical evidence (e.g., evidence-based guideline or peer-reviewed literature) supporting the safety and effectiveness of the higher dose for the member's specific diagnosis and clinical circumstances; *AND*
6. For requests to optimize dosing during medication initiation or titration, ALL of the following:
    a. The requested quantity is necessary to achieve the initial or target therapeutic dose and/or frequency per FDA-approved labeling or recognized compendia; *and*
    b. The dose optimization cannot be achieved using commercially available dosage strengths and/or package sizes within the Plan's standard quantity limit; *and*
    c. The prescriber has submitted a dose titration schedule outlining the starting dose, titration amounts and intervals, and goal maintenance dose, along with the anticipated duration of the titration period.

If the above medical necessity criteria for initial authorization are met, the requested medication may be approved for up to 12 months (or up to 3 months for dose optimization).[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Quantities Exceeding Established Plan Limits

The Plan considers medication quantities exceeding established Plan limits medically necessary when ALL of the following criteria are met:

1. The member continues to have a documented diagnosis for the requested medication that is supported by ONE (1) of the following:
    a. FDA-approved labeling; *or*
    b. Nationally recognized compendia; *or*
    c. Clinical practice guidelines from nationally recognized professional associations or governmental agencies; *or*
    d. Peer-reviewed medical literature from a major scientific or medical publication; *AND*
2. The prescribed age, dose, frequency, and duration of therapy continue to be consistent with ONE (1) of the following:
    a. FDA-approved labeling; *or*
    b. Nationally recognized compendia; *or*
    c. Clinical practice guidelines from nationally recognized professional associations or governmental agencies; *or*

    d. Peer-reviewed medical literature from a major scientific or medical publication; *AND*
3. The member has demonstrated a positive clinical response to therapy at the requested dose and quantity, as evidenced by ONE (1) of the following:
    a. Improvement or stabilization of signs and symptoms of the underlying condition; *or*
    b. Improvement or stabilization of functional status; *or*
    c. Disease remission or lack of disease progression; *AND*
4. The prescriber provides a rationale for continuing treatment at the requested dose and quantity that exceeds the Plan's established limit, considering the member's clinical status, response to therapy, and any relevant factors such as:
    a. Changes in the member's weight, metabolism, absorption, or disease severity that necessitate a higher dose; *or*
    b. Continued need for a higher dose to maintain therapeutic efficacy or prevent disease progression; *or*
    c. Inadequate response or loss of efficacy at the Plan's quantity limit; *AND*
5. The member has not experienced any treatment-limiting adverse effects or drug toxicity that would preclude continued use of the requested medication at the prescribed dose and quantity.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Quantity Limits for Medical Benefit Drugs[s]

Table 1 below provides information about the maximum dosage and dosing frequency for certain physician administered drugs. Note that maximum frequency edits must also match other prespecified details such as source, age, indication, etc. For exceptions to the limits below see above Medical Necessity Criteria for Initial Clinical Review or Medical Necessity Criteria for Subsequent Clinical Review.

Table 1: Maximum Allowed Dosage and Frequencies for Select Physician Administered Drugs

Brand Name	Generic Name	Maximum Frequency*	HCPCS Code	Associated Policies
Prolia, Xgeva	denosumab	1 visit every 164 days.	J0897	Prolia and Biosimilars SGM 2026-A Xgeva and Biosimilars SGM 2152-A
Jubbonti, Wyost	denosumab-bbdz		Q5136	
Osenvelt, Stoboclo	denosumab-bmwo		Q5157	
Bomyntra, Conexxence	denosumab-bnht		Q5158	
Ospomyv, Xbryk	denosumab-dssb		Q5159	
Aukelso, Bosaya	denosumab-kyqq		Q5161	
Bildyos, Bilprevda	denosumab-nxxp		Q5162	
Enoby, Xtrenbo	denosumab-qbde		C9399, J3590	
Remicade	infliximab	1 visit every 25 days*; or* 4 visits every 164 days*; or* 5 visits every 164 days*; or* 8 visits every 164 days*; or* 1 visit every 13 days*; or* 7 visits every 164 days*; or* 5 visits every 164 days.	J1745	Remicade and Infliximab Biosimilars SGM 2182-A
Inflectra	infliximab-dyyb		Q5103	
Renflexis	infliximab-abda		Q5104	
Avsola	infliximab-axxq		Q5121	
Zymfentra	infliximab-dyyb (SC)		J1748	
Neulasta, Neulasta Onpro	pegfilgrastim	1 visit every 13 days*; or* 2 visits every 6 days.	J2506	Neulasta and pegfilgrastim biosimilars SGM 1931-A
Fulphila	pegfilgrastim-jmdb		Q5108	
Udenyca; Udenyca Onbody	pegfilgrastim-cbqv		Q5111	

Brand Name	Generic Name	Maximum Frequency*	HCPCS Code	Associated Policies
Ziextenzo	pegfilgrastim-bmez		Q5120	
Nyvepria	pegfilgrastim-apgf		Q5122	
Stimufend	pegfilgrastim-fpgk		Q5127	
Fylnetra	pegfilgrastim-pbbk		Q5130	
Entyvio	vedolizumab	5 visits every 164 days.	J3380	Entyvio SGM 2004-A

*See Appendix A for associated diagnoses with the maximum frequency.

Experimental or Investigational or unproven[s]

The use of the requested medication for any indication other than those specifically listed in this policy or supported by the FDA-approved labeling, nationally recognized compendia, clinical practice guideline, or peer-reviewed medical literature is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Use in combination with other medications or therapies not supported by the FDA-approved labeling, nationally recognized compendia, clinical practice guidelines or peer-reviewed medical literature.
- Use for a non-FDA-approved indication or an indication not supported by nationally recognized compendia, clinical practice guidelines or peer-reviewed medical literature.
- Use of a dosage form, strength, or route of administration not approved by the FDA or supported by nationally recognized compendia, clinical practice guidelines or peer-reviewed medical literature.
- Use in a population or clinical scenario not adequately represented in the supporting evidence (e.g., pediatric use when safety and efficacy have not been established in this population).
- Use for the purpose of weight loss, cosmetic improvement, or performance enhancement, unless specifically addressed in the member's benefit plan documents.

Applicable Billing Codes

Table 2	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
Denosumab Drugs	
J0897	Prolia, Xgeva Injection, denosumab, 1 mg
Q5136	Jubbonti, Wyost Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg
Q5157	Osenvelt, Stoboclo Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg
Q5158	Bomyntra, Conexxence Injection denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg
Q5159	Ospomyv, Xbryk Injection, denosumab-dssb (ospomyv/xbryk), biosimilar, 1 mg
Q5161	Aukelso, Bosaya Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg
Q5162	Bildyos, Bilprevda Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg
C9399	Enoby, Xtrenbo (denosumab-qbde) Unclassified drugs or biologics
J3590	Enoby, Xtrenbo (denosumab-qbde) Unclassified biologics
Infliximab Drugs	
J1745	Remicade (infliximab) Injection, infliximab, excludes biosimilar, 10 mg
J1748	Zymfentra (infliximab-dyyb) (SC) Injection, infliximab-dyyb (zymfentra), 10 mg
Q5103	Inflectra Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Q5104	Renflexis Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
Q5121	Avsola

Table 2	
CPT/HCPCS codes considered medically necessary if criteria are met:	
Code	*Description*
	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
Pegfilgrastim Drugs	
J2506	Neulasta, Neulasta Onpro Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
Q5108	Fulphila Injection, pegfilgrastim-jmdb (fulphila), biosimilar, 0.5 mg
Q5111	Udenyca; Udenyca Onbody Injection, pegfilgrastim-cbqv (udenyca), biosimilar, 0.5 mg
Q5120	Ziextenzo Injection, pegfilgrastim-bmez (ziextenzo), biosimilar, 0.5 mg
Q5122	Nyvepria Injection, pegfilgrastim-apgf (nyvepria), biosimilar, 0.5 mg
Q5127	Stimufend Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Q5130	Fylnetra Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg
Other Drugs	
J3380	Entyvio Injection, vedolizumab, intravenous, 1 mg

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Appendix A

Generic Name	Maximum Frequency	Associated Diagnoses
denosumab	1 visit every 164 days	1. Glucocorticoid-induced osteoporosis*; or* 2. Intolerance to other available osteoporosis therapy*; or* 3. Osteoporosis in men*; or* 4. Postmenopausal osteoporosis prophylaxis*; or* 5. Postmenopausal osteoporosis treatment*; or* 6. Postmenopausal women receiving aromatase inhibitors for early breast cancer*; or* 7. Prostate cancer patients receiving androgen deprivation therapy*; or* 8. Systemic mastocytosis.
denosumab	1 visit every 28 days	1. Prevention of skeletal-related events in individuals with multiple myeloma and in those with bone metastases from solid tumors.
denosumab	5 visits every 56 days	1. Treatment of giant cell tumor of bone that is unresectable or when surgical resection is likely to result in severe morbidity; *or* 2. Treatment of hypercalcemia of malignant that is refractory to bisphosphonate therapy
infliximab	1 visit every 25 days	1. Aortic arch syndrome (Takayasu disease)*; or* 2. Mucocutaneous lymph node syndrome (Kawasaki disease)*; or* 3. Multisystem inflammatory syndrome in children (MIS-C) post SARS-CoV-2 exposure*; or* 4. Scleritis or severe acute respiratory

Generic Name	Maximum Frequency	Associated Diagnoses
		syndrome coronavirus 2 (SARS-CoV-2) infection.
infliximab	4 visits every 164 days	1. Reiter's disease (reactive arthritis).
infliximab	5 visits every 164 days	1. Acute refractory rejection of intestine transplant*; or* 2. Fistulizing Crohn's disease for reduction in the number of draining enterocutaneous or rectovaginal fistula(s) and maintenance of fistula closure; *or* 3. Immune checkpoint inhibitor-related toxicity (diarrhea)*; or* 4. Immune checkpoint inhibitor-related toxicity (inflammatory polyarthropathy)*; or* 5. Inflammatory polyarthropathy*; or* 6. Polyarteritis nodosa*; or* 7. Psoriatic arthritis; or 8. Severely active Crohn's disease - induction and maintenance of clinical remission in those with inadequate response to conventional therapy
infliximab	8 visits every 164 days	1. Ulcerative colitis (adult).
infliximab	1 visit every 13 days	1. Acute refractory rejection of intestine transplant*; or* 2. Adult-onset Still disease*; or* 3. Ankylosing spondylitis (adult)*; or* 4. Behcet's syndrome*; or* 5. Hidradenitis suppurativa*; or* 6. Immune checkpoint inhibitor-related toxicity (colitis)*; or* 7. Immune checkpoint inhibitor-related toxicity (diarrhea)*; or* 8. Immune checkpoint inhibitor-related toxicity (elevated serum creatinine/acute kidney injury, myocarditis, pneumonitis)*; or* 9. Immune checkpoint inhibitor-related toxicity (inflammatory polyarthropathy)*; or* 10. Immune checkpoint inhibitor-related toxicity (uveitis)*; or* 11. Inflammatory polyarthropathy*; or* 12. Juvenile idiopathic arthritis*; or* 13. Plaque psoriasis (adult or pediatric)*; or* 14. Polyarteritis nodosa*; or* 15. Psoriatic arthritis*; or* 16. Pustular psoriasis*; or* 17. Pyoderma gangrenosum*; or*

Generic Name	Maximum Frequency	Associated Diagnoses
		18. Regional enteritis (adult or pediatric)*; or* 19. Reiter's disease (reactive arthritis)*; or* 20. Rheumatoid arthritis*; or* 21. SAPHO syndrome*; or* 22. Sarcoidosis*; or* 23. Synovitis*; or* 24. Uveitis*; or* 25. Uveitis associated with Behcet's syndrome.
infliximab	7 visits every 164 days	1. Aortic arch syndrome (Takayasu disease) 2. Hidradenitis suppurativa*; or* 3. Rheumatoid arthritis*; or* 4. Sarcoidosis*; or* 5. Scleritis*; or* 6. Synovitis.
infliximab	7 visits every 164 days	1. Regional enteritis (pediatric)*; or* 2. Ulcerative colitis (pediatric).
infliximab	5 visits every 164 days	1. Regional enteritis (adult).
infliximab	1 visit every 7 days	1. Acute graft-versus-host disease.
pegfilgrastim	1 visit every 13 days	1. Chemotherapy-induced neutropenia prophylaxis in patients with non-myeloid malignancies.
pegfilgrastim	2 visits every 6 days	1. Hematopoietic syndrome of acute radiation syndrome (H-ARS).
vedolizumab	5 visits every 164 days	1. Graft-versus-host disease (acute) following hematopoietic cell transplantation*; or* 2. Immune checkpoint inhibitor-related toxicity (colitis)*; or* 3. Immune checkpoint inhibitor-related toxicity (diarrhea)*; or* 4. Immune checkpoint inhibitor-related toxicity (duodenitis)*; or* 5. Immune checkpoint inhibitor-related toxicity (esophagitis)*; or* 6. Immune checkpoint inhibitor-related toxicity (gastritis)*; or* 7. Microscopic colitis*; or* 8. Pouchitis*; or* 9. Regional enteritis (including Crohn's disease)*; or* 10. Ulcerative colitis.

Clinical Guideline Revision / History Information

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