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Medication Policy Manual **Policy No:** dru789

Topic: Products without individual medication policies subject to Site of Care review **Date of Origin:** October 1, 2024

Committee Approval Date: October 2, 2025 **Next Review Date:** 2026

Effective Date: January 1, 2026

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

Description

This policy lists medications that require prior authorization (PA) as part of the Infused Drug Site of Care (IDSOC) program but do not have their own individual medication policies.

This policy applies to fully insured commercial and exchange plans, and the Washington State Health Care Authority (with the exception of Uniform Medical Plan Plus), based in Washington, Oregon, Idaho, and Utah. This policy may apply to other self-insured groups [a.k.a. administrative services only (ASO), depending on the group-specific benefit]. This policy does **not** apply to Medicare plans.

Policy/Criteria

I. Continuation of therapy (COT): Products listed in *Table 1* may be considered medically necessary for COT when full policy criteria below are met, including Site of care administration requirements (see below).

Please note: *Medications obtained as samples, coupons, or promotions, paying cash for a prescription ("out-of-pocket") as an eligible patient, or any other method of obtaining medications outside of an established health plan benefit (from your insurance) does NOT necessarily establish medical necessity. Medication policy criteria apply for coverage, per the terms of the member contract with the health plan.*

II. New starts (treatment-naïve patients): Products listed in *Table 1* may be considered medically necessary when Site of Care administration requirements are met [refer to Medication Policy Manual, Site of Care Review, dru408].

III. Limitations and Authorization Period.

A. Regence Pharmacy Services considers the products listed in *Table 1* coverable only under the medical benefit (as provider-administered medications).

B. Authorization **may** be reviewed annually. Clinical documentation (such as chart notes) must be provided to confirm that current medical necessity criteria are met.

Table 1: Products without individual medication policies subject to Site of Care review

Medication	Effective Date	HCPCS
Benlysta IV, belimumab	10/1/2024	J0490
Trogarzo, ibalizumab-uiyk	10/1/2024	J1746

Position Statement

- New pharmaceuticals requiring infusion therapy may be administered safely, effectively, and much less costly outside of hospital-based infusion centers (a.k.a. hospital outpatient settings). Sites of care such as doctor's offices, infusion centers, home infusion, and approved hospital-based infusion centers are well-established, accepted by physicians, and provide the best value to patients to reduce the overall cost of care.
- A site of care exception for an infusion at an unapproved site of care location must be requested by the provider and reviewed by the health plan prior to administration of the infused medication, per the terms of the member contract with the health plan.

Revision History

Revision Date	Revision Summary
10/2/2025	No criteria changes with this annual review.
6/20/2024	New policy effective 10/1/2024.

Drug names identified in this policy are the trademarks of their respective owners.