

Minimizing Waste by Maximizing BUDs: Immediate Use Compounding for Biologics

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Objectives

- Introduction to Providence Infusion & Pharmacy Services
- Examine range of beyond-use dates (BUDs) and cost per dose of biologics administered via IV infusion
- Discuss USP <797> requirements for Immediate Use compounding

Audience Poll

Do you take part in dispensing, ordering, or administering biologics via IV infusion?

Providence Infusion and Pharmacy Services

- Providence St. Joseph Health System
- Home Infusion established in 1993
- Four business lines
 - Home Infusion
 - Manufacturing- 503B Outsourcing Facility
 - Long-term Care Pharmacy
 - Clinical Nutrition
- Four separate cleanrooms
- The Joint Commission accreditation since 1995

Providence Infusion and Pharmacy Services

- Home Infusion Business Line
 - Serves ~1300 patients across western Washington state
 - Therapies
 - Biologics
 - Antibiotics
 - Total parenteral nutrition (TPN)
 - Patient controlled analgesia (PCA)
 - Intravenous hydration
 - Hazardous drugs
 - Miscellaneous (e.g., inotropic agents, immune globulin)

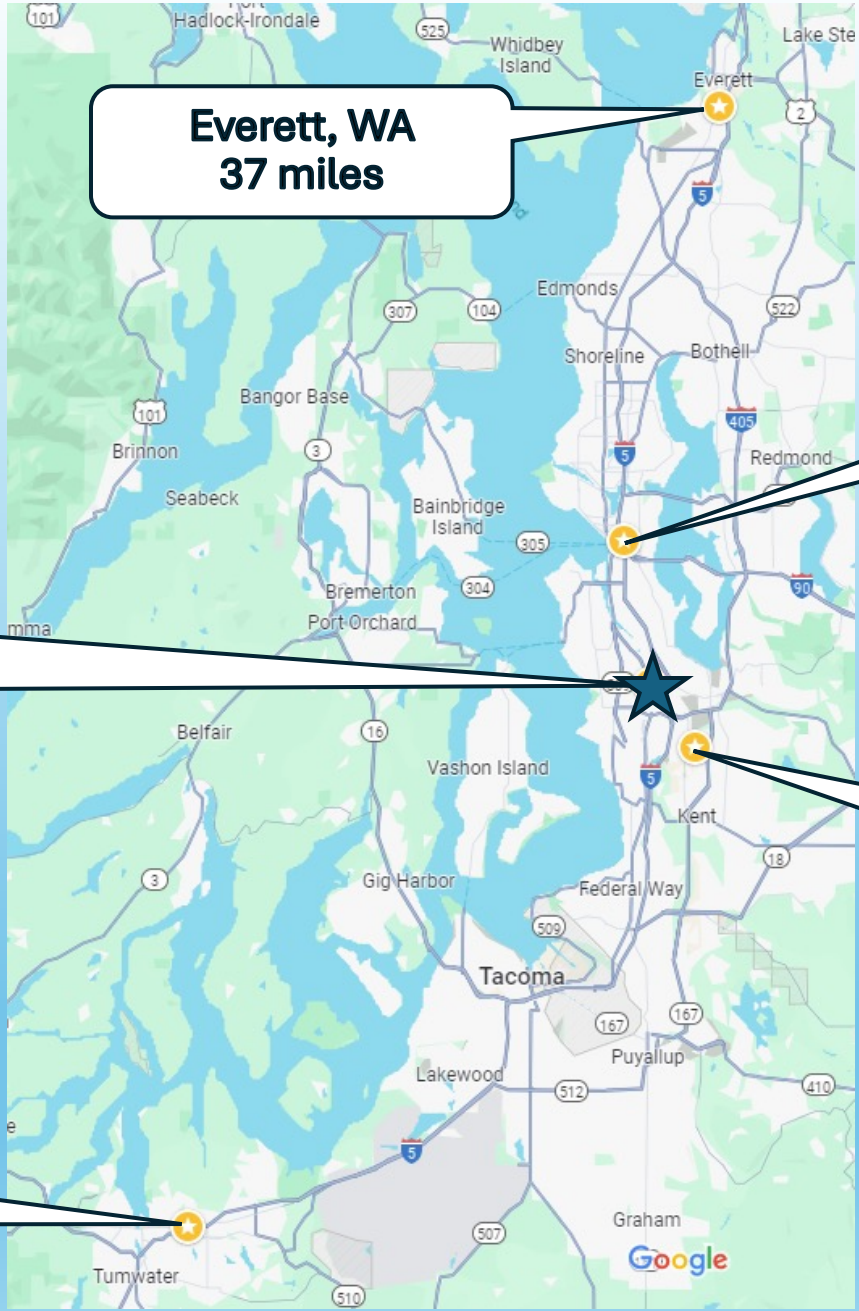
Ambulatory Infusion Suite (AIS) – Seattle



Ambulatory Infusion Suites (AIS)

Providence Infusion & Pharmacy Services (Tukwila, WA)

**Olympia, WA
50 miles**



**Everett, WA
37 miles**

**Seattle, WA
9.8 miles**

**Renton, WA
6 miles**

Top 5 Biologics Dispensed Providence Infusion & Pharmacy Services

Drug	AWP per dose (70kg adult)	Maximum Beyond Use Date if compounded in a clean room
Infliximab	\$4,587.99	3 hours after reconstitution
Vedolizumab	\$10,399.90	24 hours refrigerated
Natalizumab	\$9,851.22	8 hours refrigerated
Ocrelizumab	\$47,314.52	24 hours refrigerated
Blinatumomab*	\$37,045.14	10 days refrigerated*

*Blinatumomab compounded by HD-trained personnel in ISO 5 LAFW within ISO 7 buffer room per product criteria

Most Expensive Biologics Dispensed Providence Infusion & Pharmacy Services

Drug	AWP per dose (70kg adult)	Maximum Beyond Use Date if compounded in a clean room
Ravulizumab	\$84,532.80	24 hours refrigerated
Inebilizumab-cdon	\$164,514.35	24 hours refrigerated

Benefits of Immediate Use Compounding

- Allows time for unforeseen delays
 - Transport, delivery, heavy traffic
 - Patient preparation: line patency, pre-meds
- Decreases risk of drug waste if appointment is cancelled

Question 1

Which of the following provides standards for sterile compounding including those for Immediate Use?

- a. USP <795>
- b. USP <797>
- c. USP <825>
- d. USP <71>

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USP <797> (2023)

Immediate Use Compounding Criteria

- ✓ Aseptic techniques, processes, and procedures
- ✓ Clearly written SOPs to minimize contamination risk and mix-ups
- ✓ Training and competency
- ✓ Evidence-based information for physical and chemical compatibility of drugs

USP <797> (2023)

Immediate Use Compounding Criteria (cont'd)

- ✓ Not more than 3 different sterile products
 - ✓ All products must be sterile
 - ✓ Previously not more than 3 sterile ***packages***
 - ✓ Previously not more than 2 entries into any one package

USP <797> (2023)

Immediate Use Compounding Criteria (cont'd)

- ✓ Single-dose containers → 1 patient ONLY
- ✓ BUD: Start of infusion \leq 4 hours after start of compounding
 - ✓ Previously BUD \leq 1 hour
- ✓ Labeling: CSP must be labeled appropriately unless being administered by the preparer

Question 2

A nurse plans to compound an order for vendolizumab 300mg to be administered that day. If the infusion is scheduled to start at 1pm, what is the earliest the drug vial can be reconstituted based on USP <797> Immediate Use compounding standards?

- a. 8am
- b. 9am
- c. 10am
- d. 11am

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A nurse plans to compound an order for vendolizumab 300mg to be administered that day. If the infusion is scheduled to start at 1pm, what is the earliest the drug vial can be reconstituted based on USP <797> Immediate Use compounding standards?

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Takeaways: Immediate-Use Compounding for Biologics

- Immediate use compounding procedures may be used to significantly minimize waste of biologics administered via IV infusion
- Must observe USP <797> standard criteria for Immediate Use compounding

Questions?

References

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- USP chapter <797> pharmaceutical compounding – sterile preparations (2008)