

Quick Guide:

Qualities of a Gender-Affirming Pharmacy

KNOWLEDGABLE AND PATIENT-CENTERED CARE



Considerations for hormone therapy

Many transgender and gender diverse patients come to the pharmacy for hormone therapy as part of their gender transition. Information about hormone therapy in transgender patients is missing from many clinical resource tools that you may use in practice. A list of online clinical guidelines at the end of this section will help you counsel your patients on what to expect from their hormone therapy. These resources will also help you determine if there are interactions with other medications or conditions that warrant additional monitoring.

For injectable medications, there are multiple formulations available. Though rare, a patient may be allergic to the oil used to suspend their medication.

Make sure your patient understands the signs of an allergic reaction and help facilitate communication with their prescriber if they need an alternate therapy or route of administration.

ACCESS TO HORMONE THERAPY

There are certain situations that can create barriers to patients accessing hormone therapy. Insurance challenges, transitions of care or manufacturing shortages can result in interruptions to hormone therapy. These interruptions may result in negative physical and psychological consequences for patients. Be proactive when challenges arise by communicating with the patient and their provider. If products are on backorder, consider reaching out to other pharmacies in the area or exploring alternate therapeutic options with the patient's provider.

USP 797 AND DAYS SUPPLY CONSIDERATIONS

Recent updates to standards regarding sterile medications have created a difficult balancing act between regulatory compliance, patient safety and access. Inconsistent management between pharmacies can create confusion for pharmacists, patients, and other providers.

ADDITIONAL RESOURCES

This quick guide is excerpted from *Providing Inclusive Care and Services for the Transgender and Gender Diverse Community: A Pharmacy Resource Guide* published by the Human Rights Campaign and the American Pharmacists Association. For the full guide and other quick guides focused on the six qualities of a gender-affirming pharmacy, visit thehrccfoundation.org/TransPharmacyGuide.



1 Knowledge of key LGBTQ terms



4 Visible symbols of support



2 Inclusive communication



5 Staff training



3 Gender-related data management



6 Knowledgeable and patient-centered care

EXPIRATION DATE VS. BEYOND-USE-DATE⁷

The **expiration date** is the date after which an unopened multi-dose vial should not be used. This is designated by the manufacturer on the medication packaging.

The **beyond-use-date** (BUD) is the date after which an opened multi-dose vial should not be used. The BUD should never exceed the expiration date specified by the manufacturer.

The United States Pharmacopeia recommends the following beyond-use-date guidelines for multi-dose vials of sterile pharmaceuticals:⁸

- If a multi-dose vial has been opened or accessed (e.g., needle-punctured), it should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.

SINGLE-DOSE OR MULTI-DOSE VIAL

Even if an injectable medication contains a preservative, it may be labeled as a single-dose vial and should only be accessed one time to administer medication. This will have an impact on the days supply for the medication you are dispensing.

RX only
1mL
Single-dose vial

For example: If a patient injects 0.5 mL once weekly and their 1 mL vial is labeled as an SDV, this vial would have a 7-day supply and any remainder after 1 dose should be discarded.

ONE 10mL
STERILE
MULTIPLE-
DOSE VIAL

If you have questions about medication labeling and how it impacts patient use, reach out to the manufacturer.

5 mL
MULTIPLE-
DOSE VIAL

⁷Centers for Disease Control and Prevention, "Questions about Multi-dose vials," June 20, 2019, www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html

⁸The United States Pharmacopeial Convention, "United States Pharmacopeia General Chapter 797, Pharmaceutical Compounding – Sterile Preparations," 2008.

BEST PRACTICES FOR DISPENSING AND BILLING

- Reach out to your supervisor or district manager for your company's policies and practices when dispensing and billing for sterile injectable medications.
- Obtain an Rx for injection supplies to allow you to bill the patient's insurance. Combining Rx's may reduce cost for patients.
- Consider that injectable controlled substances such as testosterone may not be overfilled to accommodate minor self-administration errors. Patients may not be able to administer two 0.5 mL doses in full from a 1 mL vial, even with good technique.
- Be transparent with your patients about the regulatory challenges that accompany sterile injectable medications. Do not pass blame to their insurance company or prescriber. If a large vial MDV is dispensed, such as 10 mL, document that there has been a conversation about USP 797's BUD regulations with the patient and the prescriber.
- Prioritize patient safety and access to their medications. If regulatory requirements cause an increase in cost for patients, help connect them with coupon cards or financial assistance, or work with their prescriber to find a solution.
- When challenges arise, work with the patient and their prescriber to find a mutually agreeable solution.

NEEDLE SIZING AND INJECTION TECHNIQUE COUNSELING

Luer-Lok Syringe 1 mL	
Drawing Needle 18-23G 1-1 1/2 inch	
Admin Needle (IM) 22-25G 1-1 1/2 inch	Admin Needle (SQ) 25G or smaller 5/8 - 1 inch



Ensure you are providing appropriate counseling for the injection method of choice. Though manufacturers often list “for intramuscular use only” on medication packaging, there has been a recent shift to administer hormones subcutaneously that is supported both by pharmacokinetic data and patient experience.^{9,10}

Patients or their providers may have a specific preference for subcutaneous or intramuscular injection.

- If patients prefer smaller gauges, inform them that they will require a longer injection time. Counsel patients to press firmly on the plunger but inject slowly to avoid irritation at the injection site due to the increased force of the medication entering the tissue. (If 1 mL syringes are not available, discuss using 3 mL syringes with the patient. Some patients may prefer 3 mL syringes).
- Provide a patient-friendly handout, such as the [Fenway Health Injection Guide](#)¹¹
- If possible at your site, offer medication administration services for those who have needle anxiety or technique concerns.

⁹David M. Wilson, et al. “Pharmacokinetics, safety, and patient acceptability of subcutaneous versus intramuscular testosterone injection for gender-affirming therapy: A pilot study,” *American Journal of Health-System Pharmacy*, March 15, 2018 (pp. 351–358). Available at: doi.org/10.2146/ajhp170160

¹⁰Daniel I. Spratt, et al. “Subcutaneous Injection of Testosterone Is an Effective and Preferred Alternative to Intramuscular Injection: Demonstration in Female-to-Male Transgender Patients,” *The Journal of Clinical Endocrinology & Metabolism*, July 1, 2017 (pp. 2349–2355). Available at: doi.org/10.1210/je.2017-00359

¹¹Fenway Health, “Transgender Health Injection Guide,” fenwayhealth.org/wp-content/uploads/MG-6_TransHealth_InjectionGuide.pdf