Pharmacy Pearls

Biologics & Biosimilars

May 2026

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Basics of Biologics & Biosimilars

1. **Biologics** are used to treat a wide range of **chronic and immune-mediated conditions** including psoriasis and other dermatologic diseases, inflammatory bowel disease, and rheumatoid arthritis.
2. Biologics are **large, complex molecules** derived from living systems such as bacteria, yeast, or animal cells.
3. **Biosimilars** are **highly similar to** and have **no clinically meaningful differences** from an **FDA-approved reference biologic** in terms of **safety, purity, and potency.** They offer comparable therapeutic outcomes while supporting affordability and access.
4. Interchangeable biosimilars carry an additional FDA designation that allows them to be substituted for the reference product at the pharmacy level without prescriber approval. ***Not all biosimilars are interchangeable.***

Biosimilars should be considered first-line when clinically appropriate and when supported by the patient's formulary.

Table 1. Adalimumab (Reference Product: Humira)[1]

Generic	Brand	Formulations	Notes
Adalimumab-aaty	Yuflyma	Pen, PFS[2]	Room temp stability: 30 days
Adalimumab-aacf	Idacio	Pen, PFS	Room temp stability: 28 days; Not interchangeable
Adalimumab-adaz	Hyrimoz	Pen, PFS	—
Adalimumab-adbm	Cyltezo	Pen, PFS	Contains latex
Adalimumab-afzb	Abrilada	Pen, PFS	Room temp stability: 30 days
Adalimumab-aqvh	Yusimry	Pen, PFS	Not interchangeable
Adalimumab-atto	Amjevita	Pen, PFS	—
Adalimumab-bwwd	Hadlima	Pen, PFS	Available as citrate and citrate-free
Adalimumab-fkjp	Hulio	Pen, PFS	—
Adalimumab-ryvk	Simlandi	Pen, PFS	—
***Unless noted otherwise, all biosimilar formulations are citrate and latex free; stable at room temperature for 14 days**			

Table 2. Tocilizumab (Reference Product: Actemra)[3]

Generic	Brand	Formulations	Notes
Tocilizumab-anoh	Avtozma	Pen, PFS, IV	Room temp stability: 21 days
Tocilizumab-aazg	Tyenne	Pen, PFS	Not interchangeable
Tocilizumab-bavi	Tofidence	IV	Prepared IV solutions stable 12 hours at room temp: Not interchangeable
***Unless noted otherwise, all biosimilar formulations are latex free; stable at room temperature for 14 days**			

Table 3. Ustekinumab (Reference Product: Stelara)[4]

Generic	Brand	Formulations	Notes
Ustekinumab-aauz	Otulfi	IV, PFS	—
Ustekinumab-aekn	Selarsdi	IV, PFS	—
Ustekinumab-auub	Wezlana	IV, PFS	—
Ustekinumab-hmny	Starjemza	IV, PFS	—
Ustekinumab-kfce	Yesintek	IV, PFS	—
Ustekinumab-srlf	Imuldosa	IV, PFS	Contains latex; Not interchangeable
Ustekinumab-stba	Steqeyma	IV, PFS	Room temp stability: 15 days
Ustekinumab-ttwe	Pyzchiva	IV, PFS	—
***Unless noted otherwise, all biosimilar formulations are latex free; stable at room temperature for 30 days**			

[1] Purple Book- Humira (adalimumab); [2] PFS: pre-filled syringes; [3] Purple Book- Actemra (tocilizumab); [4] Purple Book- Stelara (ustekinumab)

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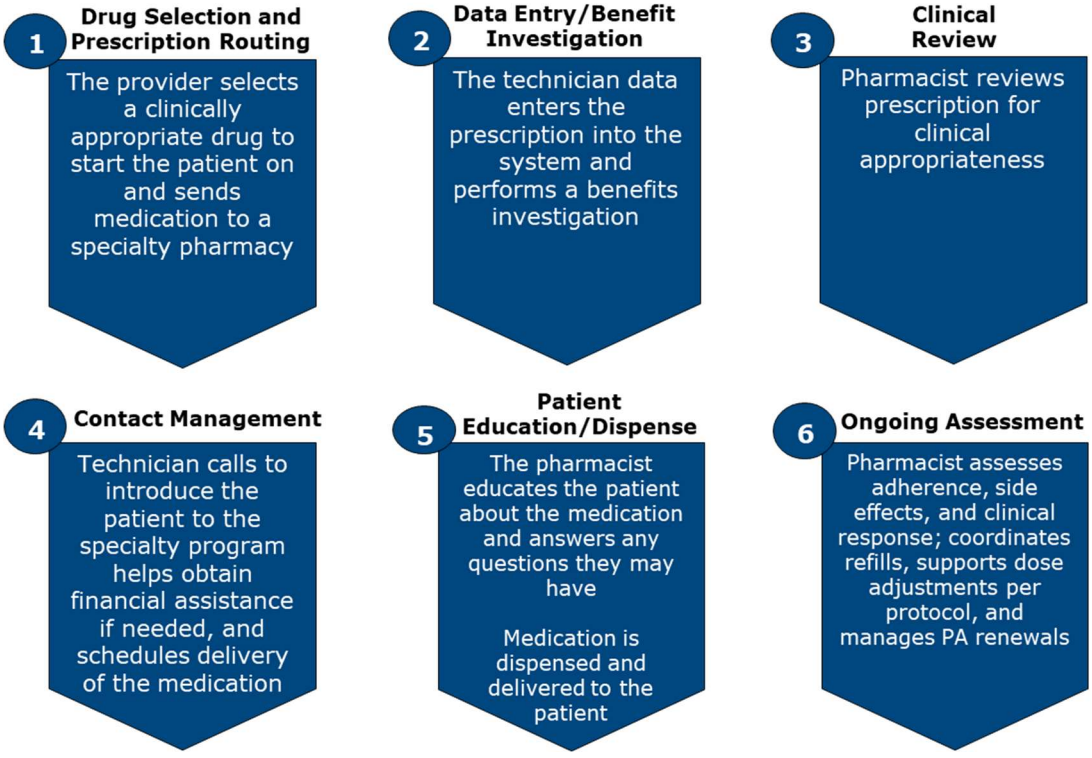
What are Specialty Medications?

Specialty medications are focused on treating rare, complex, and/or chronic health conditions. Many require special handling, administration, or monitoring. While some are oral, many must be injected or infused at home, in a clinic, or in a hospital. These medications may involve complex administration requirements, strict storage and handling, special access or authorization criteria, and high cost or financial assistance needs. Because of these factors, specialty drugs cannot typically be dispensed or supported by standard retail pharmacies and must be dispensed by a specialty pharmacy.

What is a Specialty Pharmacy?

A specialty pharmacy is a state-licensed pharmacy that primarily provides medications for patients with serious or chronic conditions requiring complex therapies. In addition to state licensure, specialty pharmacies are typically accredited by third-party organizations such as URAC®, ACHC, CPPA, or The Joint Commission to ensure consistent quality of care. Specialty pharmacies help patients access prescribed specialty medications, provide required clinical and educational support, and assist with reimbursement and financial challenges. Services often include training on medication administration, comprehensive clinical assessments, ongoing patient monitoring, and coordination with healthcare providers.

Figure 1. Specialty Pharmacy Workflow



Partnering with UR Specialty Pharmacy

- Dedicated clinical pharmacist to assist in the medication management of biologics and other high risk-therapies.
- Available to patients of prescribers under the URMC umbrella

University of Rochester Specialty Pharmacy (UR Specialty Pharmacy)

Additional Specialty Pharmacies

- Rochester Regional Health Specialty Pharmacy
  - Phone 888-512-7210
- Noble Specialty Pharmacy
  - Phone 888-843-2040
- Accredo Specialty Pharmacy
  - Phone 800-803-2523
- CVS Specialty Pharmacy
  - Phone 800-237-2767