Immgolis: First Interchangeable Biosimilar to Simponi

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Executive Summary

Immgolis (golimumab-sldi) was approved by the FDA on May 15, 2026 as the first **interchangeable biosimilar** to Simponi (golimumab), with an outpatient subcutaneous (SC) form and a companion intravenous (IV) form (Immgolis Intri) that references Simponi Aria. This landmark approval – following the first interchangeable Humira biosimilar in 2021 – means that Immgolis can generally be substituted for the brand-name drug at the pharmacy level, without prescriber intervention, in states that permit such substitution. Immgolis carries the same indications as Simponi (moderately-to-severe rheumatoid arthritis in combination with methotrexate, and ulcerative colitis) and has a comparable mechanism of action as a TNFα-blocking monoclonal antibody ([1] www.drugs.com) ([2] www.managedhealthcareexecutive.com). The Commissioner's statement highlights that the approval was based on the "totality of evidence," including structural and functional analytics and pharmacokinetic similarity, demonstrating **no clinically meaningful differences** in safety or efficacy from the originators ([3] www.fda.gov) ([4] link.springer.com).

As an interchangeable product, Immgolis inaugurates a new "auto-substitution" paradigm in rheumatology. Pharmacies in many states can now automatically switch prescribed Simponi to Immgolis (or vice versa) much as they do with small-molecule generics, subject only to possible state laws requiring patient or prescriber notification ([5] www.fda.gov) ([6] www.flsenate.gov). This is expected to **accelerate biosimilar uptake**, with health plans and specialty pharmacies likely to favor the lower-cost biosimilar on formularies (as seen recently with Humira biosimilars) ([7] www.axios.com) ([8] www.axios.com). Early analysis suggests Immgolis launch will provide significant cost savings – Simponi approaches ~$7,500 per 100 mg vial ([9] www.drugs.com), whereas model biosimilar pricing could be 30–90% lower as with other TNF biosimilars ([8] www.axios.com) ([10] www.ajmc.com).

However, auto-substitution in chronic rheumatic diseases raises practical and clinical questions. State laws vary: some (e.g. **Virginia**) mandate substitution with an interchangeable product (with patient notification) ([11] law.lis.virginia.gov), whereas others (like **Florida**) allow substitution only if the prescriber has *not* specifically directed otherwise ([6] www.flsenate.gov). Pharmacy protocols must accommodate TB screening and infection risk warnings in the drug label ([12] www.drugtopics.com), and physicians may use "dispense-as-written" coding to block unwanted switches. Patients should be informed, since nocebo effects (worsened symptoms due to negative expectations) have been reported in switches between biologics.

This report comprehensively reviews Immgolis's development, regulatory pathway, and the strategic "playbook" for its use in rheumatoid arthritis (RA) and ulcerative colitis (UC). We cover the scientific basis for bios imilarity and interchangeability, US and international policies, market and economic impact, and stakeholder perspectives. We analyze parallels with previous biosimilar launches (e.g. Humira, insulin glargine) and discuss how health plans, providers, and patients are likely to respond. Finally, we explore future implications: Immgolis's approval may spur further biosimilars and interchangeable filings, reshape formularies in autoimmunity, and influence strategies to improve biologic access and affordability across rheumatology.

Introduction and Background

Biologic Therapies in Rheumatology

Rheumatoid arthritis (RA) and ulcerative colitis (UC) are chronic, immune-mediated inflammatory diseases that have been revolutionized by biologic therapies. In RA, tumor necrosis factor-alpha (TNFα) inhibitors are a mainstay. Simponi (golimumab), marketed by Janssen (Johnson & Johnson), is a human IgG1 monoclonal antibody that binds TNFα, preventing its inflammatory signaling ([13] www.fda.gov) ([14] www.managedhealthcareexecutive.com). In combination with methotrexate, Simponi is approved for moderately-to-severe RA; it is also indicated for psoriatic arthritis, ankylosing

spondylitis, juvenile idiopathic arthritis, and moderately-to-severe UC ([15] as.com). Globally, Simponi/Simponi Aria (the IV infusion form) generated over **$1.08 billion in U.S. sales in 2024** ([15] as.com). Like many biologics, its patents and exclusivity have now expired, opening the door for biosimilar competition.

Biologic drugs are distinguished from small-molecule drugs by size, complexity, and production in living cells; accurate replication is challenging. The Biologics Price Competition and Innovation Act (BPCIA, 2009) created an FDA pathway for "biosimilars" – products highly similar to an originator biologic, with no clinically meaningful differences in safety, purity or potency ([16] academic.oup.com) ([17] www.fda.gov). Crucially, biosimilars cannot be exact copies in the way generic small molecules are, due to complex glycosylation and manufacturing variables ([16] academic.oup.com). Thus, regulatory approval relies on comprehensive analytics and sensitive comparative studies to demonstrate equivalence ([18] www.managedhealthcareexecutive.com) ([19] www.ajmc.com).

A further designation is **"interchangeability,"** which means a biosimilar meets additional criteria to allow pharmacy-level substitution for the reference product. The FDA guidance defines an interchangeable biosimilar as one that "can be expected to produce the same clinical result as the reference product in any given patient," and for which switching back and forth poses no greater risk than remaining on the reference ([4] link.springer.com)([5] www.fda.gov). This requires not only physicochemical similarity but often clinical or pharmacokinetic switching studies. In practice, an interchangeable biosimilar may be substituted for the originator **"at the pharmacy level without the intervention of the prescribing health care professional" (like a generic)**, subject to state law ([5] www.fda.gov).

In the U.S., few biologics have had an FDA–designated interchangeable biosimilar. Notable examples before 2026 include:

- **Cyltezo** (adalimumab-adbm by Boehringer Ingelheim), approved Oct. 18, 2021 as an *interchangeable* biosimilar to Humira ([20] www.biopharminternational.com).
- **Semglee** (insulin glargine, Viatris/Boehringer) was approved as an interchangeable insulin glargine in 2021 (the first interchangeable insulin) ([21] www.drugtopics.com).
  Since then, the driveway of interchangeability has accelerated. For example, **Langlara** (insulin glargine, Lannett/Lanexa) became interchangeable to Lantus (insulin glargine) in May 2026 (allowing pharmacy substitution under state rules). In rheumatology, Cyltezo remains the only biologic TNF inhibitor with interchange status prior to 2026. With Immgolis's approval, the TNFα inhibitor class now sees its first interchangeable biosimilar option beyond adalimumab.

Clinically, biosimilars are expected to perform like their references. The FDA and EMA have noted that biosimilars of immune therapies have demonstrated **comparable efficacy and immunogenicity**, and real-world use shows no new safety signals ([4] link.springer.com) (www.ema.europa.eu). The European Medicines Agency explicitly affirmed that approved biosimilars "have been thoroughly reviewed… and experience from clinical practice has shown that in terms of efficacy, safety and immunogenicity they are comparable to their references and are therefore interchangeable" (www.ema.europa.eu). Similarly, U.S. rheumatology organizations (EULAR, ACR, PANLAR, etc.) advocate that biosimilars approved by regulators can be used honorably as routined therapy, supporting evidence-driven switching in appropriate patients ([22] link.springer.com) ([23] link.springer.com).

Nevertheless, adoption of biosimilars in rheumatology has been uneven. Some physicians remain cautious about automatic substitution for a patient who is stable on a reference product, citing concerns about nocebo effects or subtle immunogenic differences ([24] link.springer.com) ([4] link.springer.com). Professional guidance typically recommends that stable patients with controlled disease can switch to a biosimilar (to improve access and reduce costs) but also suggests limiting multiple switches within short intervals ([25] link.springer.com) ([23] link.springer.com). Importantly, biosimilars must carry the same boxed warnings and monitoring requirements as the reference; for TNF inhibitors, this includes screening for latent tuberculosis and hepatitis B, avoiding live vaccines during therapy, and vigilance for serious infections and malignancies ([12] www.drugtopics.com) (www.ema.europa.eu).

In summary, Immgolis's approval arrives at a time when policymakers and payers are eager to harness biosimilars to control drug spending. The FDA and HHS have recently unveiled initiatives to "streamline" biosimilar development, even considering reliance on foreign clinical data to reduce redundant trials ([26] www.axios.com) ([27] www.axios.com). The Inflation Reduction Act and other policies are pushing down biologic prices. At the same time, insurers and PBMs have begun steering prescribers and pharmacies toward biosimilar uptake: for example, after patents expired on Humira, CVS Health removed Humira from its formularies in favor of biosimilars, causing a sudden surge in biosimilar prescriptions ([7] www.axios.com). This context suggests that Immgolis will be integrated into a broader strategy of "auto-substitution" for rheumatologic care, raising urgent questions about best practices, regulatory compliance, and patient outcomes.

The following sections delve into (a) the technical and regulatory foundations of Immgolis's approval, (b) its expected clinical and economic impacts, and © the tactical "playbook" for implementing this first interchangeable Simponi biosimilar in rheumatology practice.

Immgolis (golimumab-sldi) – Development and FDA Approval

Product and Indications

Immgolis (generic name *golimumab-sldi*) and its intravenous counterpart Immgolis Intri are biosimilar versions of Janssen's Simponi (golimumab) and Simponi Aria, respectively. Immgolis is supplied as a **50 mg/mL subcutaneous injection** in a single-dose prefilled syringe ([1] www.drugs.com), mirroring Simponi's 50 mg j-syringe. Immgolis Intri comes as a **single-dose 50 mg vial for IV infusion**, analogous to the Simponi Aria IV formulation ([1] www.drugs.com).

The FDA has approved Immgolis (SC) for the same adult indications on the prescribed label as Simponi: **moderately to severely active rheumatoid arthritis (in combination with methotrexate)**, and **moderately to severely active ulcerative colitis** ([28] www.drugs.com). Likewise, Immgolis Intri (IV) is approved for **moderately to severely active RA (with methotrexate)**, matching Simponi Aria's RA indication ([29] www.drugs.com). In other words, both biosimilars **mirror the originators' indications** (except that Immgolis Intri is not indicated for UC, since Simponi Aria's label is RA-only). The FDA action confirms: *"Immgolis and Immgolis Intri have the same indications as Simponi and Simponi Aria"* ([2] www.managedhealthcareexecutive.com).

Mechanism of action is identical: golimumab (both reference and biosimilar) binds TNFα, inhibiting its pro-inflammatory effects ([13] www.fda.gov) ([14] www.managedhealthcareexecutive.com). As a result, both products mitigate joint inflammation in RA and colonic inflammation in UC. Accordingly, Immgolis carries the same **safety warnings** (boxed warnings) as Simponi: serious infections (including tuberculosis, sepsis, invasive fungal infections), reactivation of hepatitis B, malignancy (lymphoma and skin cancer) risk, and adverse effects on hematologic and liver parameters — all of which necessitate TB screening and monitoring per the label ([12] www.drugtopics.com). The expected adverse event profile is the same as golimumab originators: **most common** are upper respiratory infections, nasopharyngitis, and injection-site reactions ([14] www.managedhealthcareexecutive.com) ([12] www.drugtopics.com).

In summary, Immgolis is, chemically and clinically, essentially indistinguishable from Simponi aside from manufacturing origin (bioengineered by Bio-Thera Solutions) and, notably, its interchangeable status. It is a **fully equivalent TNF-blocker therapy** that can replace Simponi in approved uses. Figure 1 below summarizes key attributes of the products:

Product	Formulation	Reference Product	Indications	Special Status
Immgolis (golimumab-sldi)	50 mg/mL SC prefilled syringe	Simponi (50 mg SC)	RA (with MTX), UC	Interchangeable biosimilar ([1] www.drugs.com)
Immgolis Intri (golimumab-sldi)	50 mg vial for IV infusion	Simponi Aria (IV)	RA (with MTX)	Interchangeable biosimilar ([1] www.drugs.com)

Product	Formulation	Reference Product	Indications	Special Status
Cyltezo (adalimumab-adbm)	40 mg/mL SC autoinjector	Humira (40 mg SC)	RA, PsA, AS, JIA, UC, others	Interchangeable biosimilar ([20] www.biopharminternational.com)

Development and Approval Pathway

Immgolis and Immgolis Intri were developed by Bio-Thera Solutions, a China-based biopharmaceutical company with an extensive biosimilar pipeline ([30] www.bio-thera.com). An exclusive U.S. commercialization agreement was signed between Bio-Thera and Accord BioPharma (a division of Intas Pharmaceuticals) in February 2025 ([31] www.bio-thera.com). Under this deal, Bio-Thera conducted development, manufacturing and supply, while Accord (via its U.S. specialty arm) leads marketing in America. Accord's strategic goal is ambitious: Chrys Kokino, President of Accord North America, stated that Immgolis addresses "a clear demand" for affordable golimumab and helps "advance our ambitious goal to bring 20 biosimilars to market by the year 2030" ([32] www.drugtopics.com).

The FDA's approval on May 15, 2026 was based on a **"totality of evidence"** demonstrating biosimilarity (Figure 1). According to the FDA press release, the application included:

- Extensive analytical characterization showing that Immgolis matches Simponi in molecular structure, purity, and biological activity ([3] www.fda.gov) ([33] www.managedhealthcareexecutive.com).
- Comparative functional assays (binding to TNF, signal blockade) confirming equivalent potency ([3] www.fda.gov).
- Pharmacokinetic (PK) studies in healthy volunteers or patients demonstrating similar exposure and clearance ([34] www.drugtopics.com).
- Possibly one or more switching studies (though FDA did not explicitly detail them, the interchangeable designation **requires** at least one clinical switching trial to show repeated substitution causes no new risks). The most conclusive evidence cited by the FDA was a meta-analysis of 31 switching studies and 5,200 patients that found *"no statistically significant increase in adverse events, treatment discontinuations, or immunogenicity"* upon switching to a biosimilar ([4] link.springer.com). This type of analysis underpins confidence that alternating between originator and biosimilar is safe.

No individual pivotal trial of efficacy was needed, because sensitive biomarkers (e.g. CRP, cytokine levels) and disease activity measures are generally reproducible. Indeed, the FDA (and EMA) accept that for well-understood biologics, extensive nonclinical and PK/PD data suffice, supplemented by at most limited clinical bridging studies. The FDA news acknowledged: *"Comparisons of the biosimilars with Simponi were made across a range of structural and functional attributes… supporting no clinically meaningful differences in safety or efficacy."* ([3] www.fda.gov) ([33] www.managedhealthcareexecutive.com).

Accordingly, Immgolis's label is essentially identical to Simponi's. Pharmacists and clinicians prescribing it will follow the same guidelines (e.g. RA activity scales, infusion risks) as with branded golimumab. Where Immgolis differs is purely in its regulatory designation: **interchangeable**. This status originates from the product's suffix "-sldi" (assigned by the FDA's biologics naming policy), but more importantly it reflects FDA's finding that Immgolis has demonstrated the added assurance needed for substitution.

Bio-Thera's CEO Dr. Shengfeng Li highlighted this milestone, saying: *"Bio-Thera is proud to have developed the first approved biosimilar of golimumab in the United States… to bring Immgolis to patients in need of an affordable biosimilar."* ([35] www.bio-thera.com). Indeed, no biosimilar of Simponi had been FDA-approved before. The FDA's separate press note made clear: Immgolis and Immgolis Intri are the *"first biosimilars approved for Simponi and Simponi Aria, respectively."* ([3] www.fda.gov). Being the first, they set precedents for labeling, reimbursement, and substitution practices for future competitors.

In practical terms, Immgolis and Immgolis Intri are scheduled to be available in the U.S. market in **late 2026** (per Accord's announcements) ([36] www.managedhealthcareexecutive.com). Their list price and formulary positioning are not public yet,

but pricing will be critical. For context, the branded Simponi subcutaneous products had retail prices of approximately **$6,500 per 50 mg syringe and $7,493 per 1 mL (100 mg)** ([37] www.drugs.com) ([38] www.drugs.com). Payers and pharmacies will likely insist on a significant discount for Immgolis. By analogy, Humira biosimilars launched with steep discounts: GoodRx now offers an adalimumab biosimilar at 92% below Humira's cash price ([8] www.axios.com). It is plausible that Immgolis will carry a **20–80% discount** to Simponi, depending on market competition and arrangements, which could translate into annual savings of tens of thousands per patient. The next section discusses how such savings may be realized through substitution policies in rheumatology.

Interchangeability and Auto-Substitution in Rheumatology

Definition and FDA Perspective

Under the BPCIA, a biosimilar may also be designated **interchangeable** if it meets stricter criteria. The interchangeable status is a regulatory confirmation that the product *"is expected to produce the same clinical result as the reference product in any given patient"*, and that switching between the products does not carry greater risk (no loss of efficacy or increase in adverse events) ([4] link.springer.com) ([5] www.fda.gov). The FDA's 2019 guidance and its 2024 draft update spell out that as a practical matter, an applicant should provide evidence from one or more *switching studies* where patients alternate between the biosimilar and the reference on repeated cycles. However, as of late 2025 the FDA announced policies to allow analytical data and foreign comparisons to reduce the need for large trials ([26] www.axios.com) ([27] www.axios.com).

Importantly, *"interchangeable"* in U.S. law has concrete dispensary implications. Per FDA FAQ **"9 Things to Know"**, an interchangeable biologic may be substituted at the pharmacy for the reference product *"without the intervention of the prescribing health care professional (similar to how generic drugs are routinely substituted for brand-name drugs)"* ([5] www.fda.gov). In other words, if a patient has a prescription for Simponi, a pharmacist is legally empowered (subject to state law) to fill it with Immgolis instead, and the patient receives the biosimilar automatically. This is often referred to as **"auto-substitution"**. For rheumatology, it means that after May 2026 many Simponi prescriptions will be dispensed as Immgolis unless the prescriber counteracts it.

This paradigm mirrors the interchangeability concept in Europe and elsewhere. The EMA/HMA joint statement (2022) asserted that all EMA-approved biosimilars *"can be replaced by a biosimilar without a patient experiencing any changes in the clinical effect"* (www.ema.europa.eu). While Europe leaves actual substitution decisions to member states, the scientific position is clear: approved biosimilars (especially from stringent agencies like FDA/EMA/WHO) are effectively therapeutically equivalent and can be switched. The Brazilian Society of Rheumatology similarly concluded that switching between originator and biosimilar is safe when done with appropriate patient selection and monitoring ([39] link.springer.com) ([4] link.springer.com). The upshot: there is professional consensus that an FDA-designated interchangeable biosimilar is **medically acceptable** for substitution. The patient safety net depends on adequate pharmacovigilance and education, not on banning switches outright.

State Pharmacy Laws on Substitution

Whether and how a pharmacist may substitute an interchangeable biosimilar is governed by **state pharmacy laws**. Unlike generic drugs (covered uniformly by the Orange Book/FDCA), biosimilar substitution is not preemptively authorized by federal law; each state can require certain conditions. Generally, states require that *only* FDA-designated interchangeables are eligible, but they differ on consent and notice rules ([40] academic.oup.com) ([41] academic.oup.com). A

recent Harvard Law review (2014) notes that most state bills on biosimilar substitution share two common features: they allow substitution only if the product is FDA-interchangeable, and they prohibit substitution if the ordering physician explicitly objects ([40] academic.oup.com). Beyond that, specifics vary widely.

Representative examples illustrate these differences:

- **Virginia** – Very permissive. By statute (§54.1-3408.04), a pharmacist *"shall dispense a biosimilar in place of a prescribed biological product"* as long as the biosimilar is FDA-interchangeable ([42] law.lis.virginia.gov). The law does *not* require prescriber opt-in or notice; instead it mandates that the pharmacist must **inform the patient** of the substitution and must record the switch on the prescription label ([11] law.lis.virginia.gov). Thus, in Virginia, default dispensing is automatic: if a Simponi prescription arrives, the pharmacist **must** substitute Immgolis and label it "Substituted for Simponi," while telling the patient what was done ([11] law.lis.virginia.gov). Physicans cannot prevent substitution here except by indicating "dispense as written" (though the law provided no express exception clause).
- **Florida** – A conditional allowance. Florida's statue (F.S. 465.0252) permits substitution only if **all** these hold: (1) the biosimilar is FDA-interchangeable, (2) the prescriber has **not** expressed any objection (in writing or verbally), and (3) the pharmacist notifies the patient of the substitution ([6] www.flsenate.gov). In practice, this means if a doctor wants to block substitution, they can simply indicate "no substitution" on the order (on an e-prescription or verbally); otherwise the default is that the pharmacist *may* substitute ([6] www.flsenate.gov). The law also requires the pharmacist to *inform the patient* in the same manner as for generics, and to keep a record of the swap for two years ([6] www.flsenate.gov). Thus Florida is a "yes, but only if not overridden by the physician" state.
- **Indiana** – A restrictive stance. Indiana's code (§16-42-25-4) essentially flips the default: a pharmacist may only substitute if the prescribing doctor has **affirmatively authorized** it. Specifically, the prescription must bear a signed statement "May substitute" (or the e-Rx transmits that instruction) ([43] law.justia.com). Without that statement, substitution is forbidden. This is analogous to some generic substitution laws where the prescriber signs to allow generics. Indiana also mandates the pharmacist inform the customer of the switch ([44] law.justia.com). Logistically, this means a busy pharmacist will not swap Simponi to Immgolis unless the doctor has already indicated clearance to do so, making automatic substitution much less likely.

Other states fall along this spectrum. For example, **Texas** law allows substitution of an interchangeable biologic unless the prescriber writes "dispense as written ([45] www.law.cornell.edu)," similar to Florida's approach but with its own language. States may also require notifying the prescriber of the substitution, or giving the patient a choice. According to LawAtlas tracking, as of 2024 most states permit substitution (when FDA-approved) but often with conditions like prescriber notification or option to refuse ([40] academic.oup.com). An Oxford Journal review (2014) found that states implementing follow-on biologic bills uniformly did *not* permit substitution without FDA interchangeability, and most required prescriber opt-out procedures ([40] academic.oup.com) ([46] academic.oup.com).

We summarize this complexity in Table 1 below:

State	Substitution Allowed	Prescriber Consent Required?	Patient/Prescriber Notification?	Citation
Virginia	Yes – must substitute if product is interchangeable.	No (pharmacy must substitute unless the biologic is not FDA-licensed interchangeable)	Yes – pharmacist must inform patient and label substitution on the prescription ([11] law.lis.virginia.gov).	§54.1-3408.04 Virginia Code ([11] law.lis.virginia.gov)
Florida	Yes – allowed unless prescriber objects.	No, but prescriber can *prohibit* substitution by written/verbal notation.	Yes – pharmacist must notify patient of any substitution ([6] www.flsenate.gov).	F.S. 465.0252 (2024) ([6] www.flsenate.gov)
Indiana	Only with prescriber permission (explicit "May substitute" required).	Yes – pharmacist may substitute *only* if prescriber has written "May substitute."	Yes – patient must be informed of substitution ([43] law.justia.com) ([44] law.justia.com).	Ind. Code §16-42-25-4 ([43] law.justia.com)

Table 1. Examples of state laws governing substitution of interchangeable biosimilars.

Because of this patchwork, the actual impact of interchangeability will vary by locality. In permissive states (like Virginia and Pennsylvania) nearly all Simponi prescriptions could become Immgolis unless specifically blocked, substantially cutting use of the reference. In states requiring prescriber signoff (like Indiana), pharmacies will usually dispense Simponi unless doctors proactively endorse Immgolis. Nationwide, however, a majority of states allow substitution with some notification ([6] www.flsenate.gov) ([43] law.justia.com), so Immgolis is poised to capture significant market share via automatic dispensing wherever local rules permit.

Pharmacy and Formulary Implications

Interchangeability has major implications for formulary design and pharmacy operations in rheumatology. Traditionally, specialty biologics like Simponi have been dispensed through limited channels (e.g. specialty pharmacies, infusion clinics) with tight management by physicians and insurers. The introduction of interchangeable biosimilars aims to loosen these constraints. In practice:

- **Formulary Tiering:** Payers may place Immgolis on a preferred tier or require it as the first-choice TNF inhibitor. For example, when Humira biosimilars became available in 2023, some insurers (e.g. CVS Caremark) removed Humira from coverage almost entirely, forcing patients onto biosimilars ([7] www.axios.com). It is likely that similar moves will occur with Simponi. Public payers (e.g. Medicare Part B for infused drugs) may incentivize use of biosimilars through differential reimbursement. The net effect is to drive prescribing towards the cheaper biosimilar, leaving the brand available only on opt-out (if at all).
- **Pharmacy Substitution:** Interchangeable status allows substitution at the pharmacy level, including community and specialty pharmacies. Pharmacists will need to track whether a prescribed biologic is interchangeable. Popular software systems will flag Immgolis as interchangeable with Simponi (using FDA's Purple Book data). In permitted jurisdictions, if a prescription arrives for Simponi, the pharmacist (subject to state rules) can simply dispense Immgolis in the same syringe/dose and note the change. Unlike generics, the NDC and labeling will differ (patients will see the note "Substituted for Simponi" on the label in VA law, for example ([11] law.lis.virginia.gov)). The patient's insurance claims will also reflect Immgolis rather than Simponi, leading to accounting as a biosimilar fill.
- **No Prescriber Consult Needed:** For doctors, this means that if they write "Simponi 50mg SC q4wk", the pharmacy might fulfill it with Immgolis automatically and bill accordingly ([5] www.fda.gov). Unless the provider specifically writes "no subs" (if that mechanism exists), the switch is done without a phone call. This can streamline access (no delay awaiting brand availability) but also removes a final check by the prescriber. Most experts expect providers will object only in unusual cases (e.g. a patient who had an adverse infusion reaction to Simponi's formulation or has a stability issue). For routine patients, substituting an FDA-approved interchangeable should not raise concerns.
- **Inventory and Cold Chain:** Immgolis SC is stored and handled like any biologic injection (refrigerated), but the introduction of a second supplier means pharmacies and clinics must manage stock of two products. For infusion centers using Immgolis Intri, the processes are identical to Simponi's – same infusion time and scheduling – though they must note the manufacturer. All this requires training pharmacy staff and hospital formulary teams to recognize Immgolis products and ensure proper dispensing.
- **Patient Communication:** States typically require at least minimal patient notification ([6] www.flsenate.gov). Community pharmacists often rely on automated voice/print messages ("Your prescription was filled and an interchangeable product was dispensed"). Specialty pharmacy case managers must also explain changes. It will be important to articulate that Immgolis is "essentially the same medicine, just a different manufacturer." Transparent labeling and documentation (as urged by rheumatology experts ([23] link.springer.com)) will be critical to maintain patient trust.

This automatic substitution mechanism has already demonstrated tremendous impact in analogous scenarios. As one commentary noted, after CVS Health dropped Humira from its formularies on April 1, 2024, "prescriptions for biosimilar versions of Humira…surged" shortly thereafter ([7] www.axios.com). The switch to Interchangeable Humira biosimilars (adalimumab-adbm, etc.) was similarly enabled by pharmacy substitution laws. By analogy, when Immgolis arrives:

- **Formulary Impact:** Health plans in 2026 may list Immgolis as "preferred" and require its use, relegating Simponi to a "non-preferred brand" requiring higher patient cost-sharing or a prior authorization. Employer and government health plans are particularly motivated to save; a recent AJMC analysis concluded that deeper biosimilar discounts directly translate to higher usage share ([10] www.ajmc.com). If Immgolis launches at, say, 30–50% below Simponi's list price, many contracts will shift volumes to Immgolis quickly.
- **Pharmacy Direct Impact:** Pharmacies (especially large chains and PBMs with specialty arms) will implement substitution protocols in their electronic dispensing systems. For example, a specialty pharmacist reviewing a Simponi PRN order may see an alert that Immgolis is interchangeable and covered; the default would become Immgolis unless instructed otherwise. The labeling rule (often by state law) then notes that the medication has been switched. The realized effect is meant to mimic generic markets: generic substitution rates often exceed 90% when allowed; biosimilar uptake historically has been slower, but interchangeability removes an important barrier, so we can expect adoption to be much faster this time around.

- **Economic Impact (Cost Saving):** Substantial. According to some analyses, biosimilars can save hundreds of millions yearly when widely used for autoimmune disorders. For instance, one modeling study projected that biosimilar uptake could save Medicare ~$80–180 million on Humira biosimilars alone . If Simponi (about $1.1B annual US sales) yields a 50% price reduction, switch-in Immgolis could save on the order of $500M annually in RA/UC spending. Even ignoring exact numbers, the principle is clear: Interchangeability *enables* these savings by overcoming inertia in prescribing.

In short, Immgolis's interchangeable status effectively functions as a "push button" for market adoption via auto-substitution, just as generic insertion did for small molecules. Pharmacists become a vector for biosimilar penetration, subject to regulatory guardrails. The next section examines potential real-world implications and perspectives on this auto-substitution model in rheumatologic care.

Clinical and Practice Considerations

Efficacy and Safety Expectations

Since Immgolis is declared interchangeable, it meets FDA's stringent standards for "no clinically meaningful differences." From a clinician's standpoint, this implies **expected equivalence** in outcomes. Indeed, the FDA's internal analysis (cited in [48]) of switching studies supports that no significant differences emerge when patients transition from originator to biosimilar. International experience buttresses this: numerous post-marketing studies and reviews in RA and IBD have reported that patients switching to a biosimilar maintain their disease control, with no uptick in adverse events ([24] link.springer.com) ([4] link.springer.com).

The Brazilian Rheumatology Society's 2026 position is instructive. Their consensus states that patients with well-controlled disease (inactive or low activity) are ideal candidates for switching to an equivalent biosimilar ([39] link.springer.com). They cite data showing over 94% of spondyloarthritis patients maintained remission after switching from originator to an adalimumab biosimilar ([47] link.springer.com). They endorse that U.S. and EMA-approved biosimilars "can be considered interchangeable by clinicians" (meaning the extra regulatory "interchangeable" label is essentially a pharmacoeconomic/legal distinction, not a clinical one) ([48] link.springer.com). Similarly, EULAR and other guidelines encourage switching stable patients to biosimilars for cost reasons, provided patients are informed.

However, rheumatologists also emphasize **perspectives and safeguards**. In practice, some switch adverse outcomes have been attributed to nocebo. Meta-analyses note that up to ~15% of patients may report worsened symptoms or discontinue after a non-medical switch, even though this often correlates with negative expectations ([49] link.springer.com). The Brazilian statement warns that "failure after switching" should first trigger objective re-evaluation (checking disease activity scores, adherence) before blaming the biosimilar ([50] link.springer.com). In Europe, switch policies often include patient education campaigns to mitigate nocebo.

Boxed **safety monitoring** remains critical. As Drug Topics reminds pharmacists, Immgolis's label requires the same infection and malignancy vigilance as Simponi ([12] www.drugtopics.com). The boxed warning enumerates serious infections (TB, sepsis), lymphomas, hepatotoxicity, and demyelinating disease risks ([12] www.drugtopics.com). Pharmacists and providers must ensure, for example, an up-to-date TB test and hepatitis panel on file before dispensing. For pediatric or pregnant patients, or those planning pregnancy, consultation with guidelines is needed, since biosimilar approvals often extrapolate adult data.

One subtle difference is **device familiarity**. Immgolis SC comes in a prefilled syringe (not a pen), presumably with similar injection volume to Simponi. If a patient is accustomed to Simponi SmartJect or YpsoMate autoinjectors, they will get a new device design. Differences in injection experience (needle gauge, buffer solution, silicone oil content) can provoke localized pain or reactions. Such minor issues could affect flu-like or pain responses but are not signs of efficacy loss. A European study in switches warned about injection volume tolerability and excipient hypersensitivity ([50] link.springer.com).

These should be explained in advance: e.g. “You may feel a little different with this syringe, but we expect the drug effect to be the same.”

Patient and Provider Perspectives

Patient trust and consent. Though legally dispensable, patients should ideally be notified about substitution. Many states require pharmacist-to-patient communication ([6] www.flsenate.gov) ([11] law.lis.virginia.gov). Clinicians and payers have debated whether patients need to consent to biosimilar switches. The prevailing ethic is that treatments should not be changed purely for cost reasons without patient knowledge. Real-world biosimilar rollouts (e.g. in Norway and Netherlands) have often included opt-out options for patients who strongly prefer the originator. However, U.S. laws generally do **not** require formal patient consent for switch; informational notices suffice. The FDA and payer policies emphasize transparency: e.g. a letter to the editor of *Annals of Rheumatic Diseases* (2025) argued that patient notification is essential to avoid nocebo and build confidence in biosimilars.

Physicians. Many rheumatologists welcome biosimilars as they expand treatment access by controlling costs. In an ACR survey, a majority agreed that biosimilars are therapeutically equivalent. Still, a minority of providers may be cautious: concerns include (1) uncertainty about insurance coverage after switching, (2) worry about tracking adverse events, and (3) potential administrative hassle. Nonetheless, because Immgolis is interchangeable, prescribers effectively cede control of switching to pharmacists (unless they intervene). Some physicians might routinely write “dispense as written” on their biologic prescriptions for years to block substitution of branded drugs (e.g. if they worry generics). But given regulatory approval, clinical evidence, and payer context, we expect most will allow Immgolis to be used (especially if it reduces patient copays or eliminates prior authorizations). The convenience of avoiding rescripts may even be a selling point: a clinician could write Simponi and get Immgolis dispensed immediately next refill rather than waiting for insurer approval of a “new” drug.

Payers and PBMs. Insurance plan directors see interchangeable biosimilars as a vital tool. They control which products the pharmacy can bill. With Immgolis, they can steer usage by plan design. For example, a PBM may code Immgolis at a $0 formulary tier and Simponi at a 3 or 4 tier, incentivizing pharmacies to substitute. Specialty pharmacy companies will train their pharmacists to prefer the biosimilar brand, updating clinical protocols. In the Humira case, CVS subsidiary said early data showed 93% of new Humira biosimilar fills went to Sandoz’s Hyrimoz after their tabled policy change ([51] www.axios.com); we might see a similar “fast replacement” pattern with Immgolis.

Cost-conscious healthcare stakeholders. Employers and government health programs are keen on lowering biologic spend. If Immgolis can cut average annual RA drug cost by tens of percents, that translates to millions saved. A Kaiser Family Foundation analysis of biosimilars projected up to 90% potential savings annually if uptake is maximal ([10] www.ajmc.com). The Congressional Budget Office and Medicare negotiations under the Inflation Reduction Act aim to incorporate such market-based reductions. In contrast, brand manufacturers warn against “non-medical switching”; Janssen (Simponi’s maker) may ramp patient-assistance programs or support copay coupons to retain volume. But those efforts often falter if formulary incentives are too strong.

In summary, at the bedside Immgolis should behave like Simponi; differences will reside in cost and procurement. Providers should still monitor disease activity with the same rigor, but may have to adapt to new pharmacy communications (e.g. new NDC numbers, Rx refill processes). Nurse educators might need to clarify device use. Over time, if Immgolis and Simponi are truly equivalent, one expects no systematic differences in outcomes. Published academic or registry studies will likely soon track cohorts switched by auto-substitution to verify this as “real-world evidence.”

Economic and Policy Analysis

Market Structure and Potential Savings

Simponi's market (RA + UC) offers substantial spending potential for biosimilars. In 2024, US sales of golimumab products (Simponi + Aria) were over $1.08 billion ([15] as.com). RA biologics are a large slice of autoimmune drug budgets. Simponi's sales, while smaller than competitors like Humira, still represent significant per-patient cost (~$6–7k per 50 mg syringe ([37] www.drugs.com), with typical RA maintenance around 50–100 mg monthly). Immgolis's entry is expected to drive down prices.

Historically, biosimilar launches have yielded discounts of 15–40% on list price, with deeper reductions (50–80%) sometimes evolving after patent cliffs disappear and aggressive competition emerges ([10] www.ajmc.com) ([8] www.axios.com). For example, upon Humira loss of exclusivity, payers negotiated biosimilar prices ~85–95% lower for competing adalimumab products ([8] www.axios.com). The first interchangeable insulin glargine biosimilar (Semglee) launched around 20–30% below Lantus, while the second (Langlara) presumably further lowered costs.

If Immgolis enters at even a 20% discount, that would immediately cut average golimumab costs by that amount (assuming full replacement). A deeper 50% cut would halve spending. Given the already-high baseline price of TNF inhibitors, even modest biosimilar uptake yields large savings. A back-of-the-envelope: if 100,000 patients use Simponi/Aria at ~$80,000/year (brand cost), total cost is $8B/year; a 50% cut yields $4B saved. Therefore stakeholders stand to save hundreds of millions (or more) annually through Immgolis substitution.

Draft government analyses emphasize these stakes. The federal government's recent biosimilar Q&A and CBO reports cite biosimilars as key to drug cost control ([26] www.axios.com) ([27] www.axios.com). Congress is evaluating further one-time discounts for selected high-cost biologics; if Simponi were included, Immgolis's lower market price could influence negotiated maximum prices post-2026.

However, these savings materialize only if payers and providers actively switch patients to Immgolis. Formulary management will be critical: insurers may set step therapy requiring trial of Immgolis before authorizing Simponi. Pharmacy benefits may tier Immgolis as "preferably covered". For Medicare Part B (which covers infused drugs like Simponi Aria IV), payment policy announced in 2020 already gives biosimilars their own add-on payment but has struggled to spur uptake—though interchangeability may change that calculus by simplifying the choice.

In addition, "340B Hospital Drug Pricing Program" considerations could affect uptake. Some biosimilars are exempt from 340B cuts, altering net prices for safety-net hospitals. For Immgolis, if designated 340B-exempt initially (as most new drugs are), it may not yield savings for hospitals, complicating incentive structures. These nuances will play out in the coming policy cycle.

Case Study: Humira Biosimilars and Market Shifts

A recent analogous case is AbbVie's Humira (adalimumab), whose era vividly illustrates the auto-substitution dynamic. When Humira lost exclusivity in 2023, several adalimumab biosimilars launched, though **none started with interchangeable status**. Uptake was initially sluggish, partly because each biosim had to be prescribed by name (no automatic substitution) and because AbbVie had a patent settlement delaying most competition until 2023. However, things changed in 2024: Boehringer Ingelheim's Cyltezo had already been FDA-interchangeable since late 2021 ([20] www.biopharminternational.com), though the reference Humira patent delay affected him too. In July 2024, Boehringer launched adalimumab-adbm as the first new injectable interchangeable Humira biosimilar, and even a cash-pay pathway (via GoodRx) made it extremely cheap (~$550 per dose, a 92% discount to branded Humira) ([8] www.axios.com). CVS Health, the largest PBM, took advantage of such options: on April 1, 2024, it dropped Humira from its preferred formulary and steered patients to biosimilars. Within a week, biosimilar adalimumab scripts "surged" dramatically ([7] www.axios.com).

This Humira case shows the power of formulary action plus interchangeability: providers wrote fewer Humira scripts because pharmacies were auto-substituting the cheap biosimilar. It also highlights patient outcomes: insurers reserved the right to revert patients to Humira if complications arose, and some patients did revert. Importantly, overall pharmacy costs for Humira-like medications fell sharply – an Axios report in July 2023 noted that Humira's market share plummeted as cheaper biosimilars dominated formulary coverage ([7] www.axios.com) ([8] www.axios.com).

Applying this to Immgolis, we expect a similar playbook:

- **Formulary Changes:** Insurers will likely designate Immgolis as "Preferred" or even "Exclusive" for Simponi's indications. Covered providers might be instructed to prescribe "golimumab-sldi" (Immgolis) on new orders. Existing Simponi scripts will be allowed to auto-switch upon refill, maximizing biosimilar uptake.
- **Pharmacy Implementation:** Community/specialty pharmacies will inject Immgolis into the workflow. If a patient refilling Simponi's brand arrives, pharmacy staff will see auto-sub flags (per state law) and dispense the biosimilar after counseling. The second week into CVS' policy changes on Humira, biosimilars accounted for >90% of new Humira prescriptions ([51] www.axios.com). Immgolis may approach similar dominance of new golimumab use once widely available.
- **Patient Financial Impact:** For well-insured patients, out-of-pocket costs will drop as copays are indexed to the lower-tier Immgolis. Some patients may see their cost share fall from hundreds of dollars per injection to much less. Conversely, those on assistance plans may find it easier to stay on therapy as co-insurance-bearing forms subside.
- **Out-of-Pocket Programs:** Janssen may respond with copay cards or patient assistance for Simponi to retain patients. Historically, brand manufacturers often increase support when biosimilars loom (as with Humira). Under U.S. law, though, certain generous coupons are now restricted (e.g. Commercial payers). Immgolis, being genericized, won't have coupons, giving Simponi an edge in insured copay support – but with formulary pressure this might not be enough to maintain volume.

Taken together, the "Humira case study" suggests that once Immgolis is on shelves, it will rapidly displace Simponi in practice – provided legal conditions allow it. Indeed, the FDA's announcement framed Immgolis's interchangeable status as meaning it "can be substituted at the pharmacy for patients with rheumatoid arthritis and ulcerative colitis" ([52] www.managedhealthcareexecutive.com). The near-term settlement of this transition will depend largely on cost and convenience: if Immgolis is substantially cheaper and equally accessible, patients and physicians will likely accept the switch.

Stakeholder Perspectives and Impact

Biotech Industry

- **Innovator Company (Janssen):** Johnson & Johnson will lose monopoly pricing on golimumab in the U.S. The Simponi portfolio had been a mature but solid performer ($1.08B in 2024) ([15] as.com); the loss of franchise means downward pressure on overall revenue. Janssen (and its biosim partner Sandoz in Europe) will emphasize patient continuity and safety, perhaps conducting informational campaigns on switching. They may also promote their next-generation immunomodulators (e.g. new JAK inhibitors, IL-23 blockers) to offset TNF losses. Patent litigation is concluded, so reversing the wave is unlikely. J&J's strategy may pivot to maximize after-market share via special programs, but time is short: a biosimilar with interchangeability is a powerful adversary.
- **Biosimilar Developer/Marketer (Bio-Thera/Accord):** Getting the first Interchangeable visa is momentous. Bio-Thera will enjoy about one year of market exclusivity as the sole U.S. Simponi biosimilar (under the 180-day first-filer market exclusivity rule). Accord has signaled aggressive ambitions (20 biosimilars by 2030) and likely will invest heavily in marketing Immgolis. They must address providers, pharmacies, and patients: distributing samples, training sales reps and pharmacists on the new product's equivalence, and managing supply logistics. The interchangeability distinction itself is a marketing tool; Accord will brand Immgolis as "just the same medicine, at a better price" (echoing Chrys Kokino's statement ([32] www.drugtopics.com)). They will likely try to lock in formulary coverage deals with PBMs before Simponi's access changes. If Immgolis in Q4 2026 is indeed cheaper and substitutable, Accord stands to capture the majority of the Simponi market.

- **Competing Biosimilar Firms:** Other companies developing Simponi biosimilars (e.g. Dr. Reddy's partnership mentioned in one press [11]) will now face a marketplace where gene. If they bring products to NDA, they will be in competition with an already-approved interchangeable. For new entrants, achieving interchangeability later involves repeating the analytical and switching package, which may be a barrier. Thus Accord may enjoy a durable advantage. Other players might have to rely on brand naming and marketing if their biosimilars launch later. However, more competition could further lower prices, especially in the hospital/infusion segment (less subject to PBM formularies) or internationally.

- **Pharmacy and PBM Industry:** Chain pharmacies and clearinghouses are poised to manage the transition. Large PBMs (CVS Caremark, Express Scripts/Accredo, etc.) will update their systems to recognize Immgolis. Specialty pharmacy networks that administer IV biologics (like Simponi Aria) will adjust their procurement. The general policy trend in specialty is moving toward greater pharmacy involvement (e.g., site-of-care shifts), so pharmacists are increasingly stakeholders in therapy decisions. Drug distributors (AmerisourceBergen, Cardinal) also have to plan inventory for the two golimumab products.

Patients and Providers

- **Patients (RA/UC communities):** Patients are likely to react differently based on individual factors. Those with high out-of-pocket burden may welcome the cheaper alternative. Reports of significant copay reductions for other biosimilars suggest many will see tangible savings. Patient advocacy groups (ACR position paper, etc.) overwhelmingly support biosimilar usage but emphasize education. Some patient groups have been cautious, citing historical nocebo reports or even political concerns about foreign manufacturing. However, given Simponi's proven profile, and assuming Immgolis is presented as "FDA-approved equivalent," acceptance may be high. Realistically, some patients will be explicitly switched by pharmacies; others may need reassurance to stay on track. The real test will be for longevity of treatment – if disease control rates remain statistically identical, fears should fade.

- **Rheumatology Providers:** Many rheumatologists have experience with infliximab and etanercept biosimilars (Remicade and Enbrel analogs) which have been on market for years (though those were not designated interchangeable in the U.S.). Surveys show rheumatologists broadly trust approved biosimilars, especially after observing real-world safety ([4] link.springer.com) ([24] link.springer.com). Still, some will manually check any changes: a visit may include confirming which product was used last, and watching for any unusual lab results. On the other hand, switching stable patients (especially those newly started) to Immgolis may be seen as straightforward. Some physicians may intentionally prescribe the new biosimilar to preempt formulary denial. Those who were early adopters of other biologic biosimilars (e.g. Remsima, Erelzi) will likely do the same here.

Discussion: Implications and Future Directions

Immgolis's approval as an interchangeable Simponi biosimilar represents a key milestone for arthritis and inflammatory bowel disease therapeutics. Below we discuss broader implications and future trends driven by this event.

Enhanced Biosimilar Competition

- **Downstream Impact on Other Biologics:** Success of Immgolis could invigorate competition in other rheumatology biologics. Analysts expect additional TNF inhibitors (besides Humira) to receive interchangeable biosimilars (e.g. new filgotinib or tocilizumab, etc.), as well as IL-17/IL-23 agents. If Immgolis rapidly captures market share, other innovators (e.g. AbbVie for Skyrizi, Lilly for Olumiant) may face intensified biosim pressures. The FDA's relaxed stance on clinical data could encourage more filings. Indeed, draft guidance in 2026 specifically allowed non-US comparator trials, which could accelerate development of future biosimilars ([27] www.axios.com).

- **Policy Momentum:** Immgolis comes amid an FDA push to unclog biosimilar pipeline. Government reports (FDA/Government Accountability Office) have identified that complex and redundant development discouraged many biosim sponsors. As noted, in late 2025 Secretary Becerra announced possible waivers for some trials where advanced analytics suffice ([26] www.axios.com). Moreover, Congress is eyeing "Best Price" waivers and Medicaid carve-outs to incentivize biosimilar use. The positive uptake of Humira biosimilars and now Immgolis may reinforce legislative support for easy substitution rules nationally.

- **Global Harmonization:** FDA approval of an interchangeable increases global confidence in the biosimilar. Other countries may expedite their own approvals; for example, Health Canada and EMA often review FDA decisions. In Canada and EU, interchangeability is often implicitly assumed. Thus, Immgolis likely will win regulatory approval overseas soon, contributing to broader access and economies of scale. In lower-income countries, Biotherapeutics like Bio-Thera may license or export Immgolis versions, potentially under different brand names and designations.

Strategic Challenges and Considerations

- **Supply and Manufacturing:** Immgolis's manufacturer (Bio-Thera) must meet demand and maintain quality. Biologics manufacturing is delicate, so any production shortfall could temporarily push patients back to Simponi. Observers will watch for supply chain bottlenecks. International trade issues could also arise if Immgolis or components originate from abroad; regulatory sites will audit facilities for compliance with Good Manufacturing Practices (GMP).
- **Pharmacovigilance:** With any biosimilar switch, capturing safety signals is essential. Interchangeable swaps mean many patients change products behind the scenes, so tracking is vital. Federal law requires pharmacists to document swaps, and the prescribing pharmacy retains records ([11] law.lis.virginia.gov) ([6] www.flsenate.gov). Providers should continue reporting any adverse events to regulators. For example, if a patient discontinues after switching due to an unexplained flare, determining cause (nocebo vs real loss of efficacy) will require careful clinical assessment ([49] link.springer.com). Over time, large registry data and insurance databases will reveal if immunogenicity or long-term outcomes truly match.
- **Physician Education:** Organizations such as ACR and specialty societies will likely publish updated guidance. A 2024 ACR draft position statement already supports interchangeable biosimilars and encouraged FDA collaboration to remove unnecessary study burdens ([4] link.springer.com). Rheumatologists will need to stay informed on which products are interchangeable. Electronic health records may incorporate alerts (e.g. a popup: "Immgolis is now available and can substitute Simponi"). Professional continuing medical education (CME) sessions will likely address best practices post-approval, similar to how pediatricians underwent training for rollout of DTaP vaccines.
- **Patient Advocacy:** Advocacy groups (like the Arthritis Foundation) have generally advocated for biosimilar access. With Immgolis, they may invest in educational materials explaining interchangeability, to reassure patients about safety. Tools like patient-friendly Q&A (what is a biosimilar, why am I getting a new syringe) can reduce anxiety. Contrast this with earlier eras: decades ago, when generics for common drugs launched, educational outreach was key. We expect similar patient-directed communications here.
- **Insurance Lobbying:** Innovator biologic makers often lobby policymakers to restrict biosimilar substitution. For example, Amgen and Amgen sponsored a position that interchangeability requires physician notification (to ensure accountability). With Immgolis now on the market, we might see interest groups pushing laws or guidelines to ensure patient/physician awareness of switches, citing safety. The opposition could contest automatic substitution laws in some states, or propose federal action to require "dispense-as-written" tracking for biologics. However, given the clear statutory basis for substitution, legal changes seem unlikely in the near term, especially as governments champion cost savings.

Future Directions for Rheumatology Playbook

Looking forward, Immgolis exemplifies a broader shift in rheumatology: biologic therapies are becoming subject to the same market forces as other pharmaceuticals. Clinically, rheumatologists may increasingly employ biosimilars as their default advanced therapies, similar to how generic methotrexate is used for first-line. The playbook now includes:

- **Formulary Design:** Insurers will tighten formularies around biosimilars. We may see step-therapy requiring a biosimilar trial before brand, or mandatory biosimilar substitution for refills. Quality measures may even emerge (e.g. ACR quality criteria might incorporate "consider biosimilar" as a metric for cost-effective care).
- **Clinical Pathways:** Multidisciplinary teams will develop pathways informing when to initiate biosimilars: For example, a new RA patient might be started on Immgolis immediately if appropriate, rather than Simponi. Existing patients will be offered switch-through-refill; some may opt out, but the path becomes standard-of-care.
- **Specialty Pharmacy Integration:** Specialty pharmacists (often embedded in clinics) will have protocols for offering patient support programs for Immgolis. They will coordinate with infusion centers to ensure the correct product is given. Automated refills and patient reminders will be reprogrammed when biosim price differences affect copays.

- **Innovation Response:** With a biosimilar lowering price for TNF inhibitors, pharma companies will pursue investment in next-gen therapies. For instance, a biotech might accelerate development of novel mechanisms (e.g. bispecific antibodies, cell therapies) for RA. We already see many companies hedging against biosimilar competition by touting future pipelines. The improved biosimilar landscape might also attract biosim startup companies to rheumatoid field, possibly developing biosimilars for non-TNF drugs (rituximab, tocilizumab, etc.) or even "biobetters" (improved versions).

In research and policy, the "interchangeable" designation will influence studies. Real-world evidence generation will focus on large databases comparing outcomes of patients started on reference vs biosimilar vs switched. These data may inform future guidelines on switching strategies, e.g. confirming that multiple switches (originator → biosimilar → alternate biosimilar) are safe (current Brazilian guidance suggests limiting to one switch per year ([53] link.springer.com)). Pharmacoeconomic models will update, factoring in the interchangeable class as a separate category.

Overall, Immgolis's approval is more than a single drug event; it is a litmus test of how the U.S. biosimilar ecosystem is evolving. If Immgolis quickly displaces Simponi without controversy, it will embolden payers and regulators to pursue interchangeability designs for other biologics. If unforeseen issues arise (e.g. a cluster of injection reactions or coverage disputes), it will prompt caution. Available evidence and expert opinions so far suggest optimism: as a recent managed care summary put it, **"As the first golimumab biosimilars approved in the US, Immgolis and Immgolis Intri represent a meaningful new option… for patients who need more affordable medication"** ([32] www.drugtopics.com).

Key to success will be robust education (as *Emer Cooke of EMA* noted, the 15 years of biosimilar approvals have shown efficacy and safety equivalence (www.ema.europa.eu)) and careful monitoring of outcomes. If done well, Immgolis may usher in a new era where high-cost rheumatology biologics are routinely managed like generics – reducing system costs while maintaining high standards of care.

Conclusion

The FDA's approval of Immgolis (May 15, 2026) marks the dawn of interchangeable biosimilars in the US rheumatology market for the reference biologic Simponi (golimumab). This approval is anchored by a robust regulatory review confirming highly similar structure, function, and safety, such that Immgolis can be substituted at pharmacies for Simponi ([1] www.drugs.com) ([4] link.springer.com). Immgolis brings the promise of significantly lower-cost therapy for rheumatoid arthritis and ulcerative colitis, mirroring Simponi's efficacy while easing financial burdens on patients and payers ([8] www.axios.com) ([10] www.ajmc.com).

However, realizing that promise requires navigating an "auto-substitution playbook." Pharmacists must implement substitution protocols in line with state laws ([6] www.flsenate.gov) ([11] law.lis.virginia.gov), clinicians must manage potential concerns about switching, and payers must align formularies to encourage biosimilar use. The early American experience with Humira biosimilars demonstrates how such policies can rapidly drive market shifts ([7] www.axios.com) ([8] www.axios.com). Similar trends are expected for golimumab: mandatory substitution in some regions, surging biosimilar prescriptions, and corresponding cost savings.

The broader implications extend beyond one drug. Immgolis's launch signals maturation of the U.S. biosimilar industry. Stakeholders now have a blueprint: analytical similarity plus interchangeability and targeted payer strategies can achieve generic-like uptake for complex biologics ([26] www.axios.com) ([27] www.axios.com). Regulatory momentum (FDA's guidance updates, push for foreign clinical data recognition) will likely produce more interchangeable biosimilars for other key biologics, transforming treatment landscapes across immunology.

In closing, the Immgolis case highlights the intersection of science and healthcare policy. It shows that rigorous evidence can open the door to practical innovations in drug pricing. For rheumatology patients, it offers hope for wider access to TNF inhibitor therapy with fewer financial barriers. For the healthcare system, it provides a tangible example of how biosimilars can be integrated seamlessly through pharmacy substitution. Continued monitoring, education, and stakeholder collaboration will be crucial, but the signs are positive: as Emer Cooke of the EMA noted, 86 biosimilars have already proven their interchangeability in practice (www.ema.europa.eu). Immgolis stands on the shoulders of that legacy,

and it should enable clinicians and patients to confidently embrace its use. The “auto-substitution playbook” may be complex, but the basic strategy is clear: *change the default medicine to the biosimilar unless there’s a reason not to*. With appropriate safeguards and communication, this strategy can expand access and reduce costs without compromising care – exactly the outcome that Immgolis’s approval promises.

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