

Figure 1. Checklists for workflow considerations relating to adalimumab biosimilars.

Pharmacies/Specialty Pharmacies	Specialty Clinics (e.g., rheumatology, gastroenterology, dermatology)
<ul style="list-style-type: none"> <li>□ Staff education relating to:                             <ul style="list-style-type: none"> <li>- Adalimumab biosimilar products including formulations considerations and patient resources</li> <li>- Interchangeability designation as it pertains to state law</li> </ul> </li> <li>□ Update pharmacy ordering/processing software to ensure product database is up to date</li> <li>□ Review current support for benefits investigation and prior authorization services and anticipate increased demand/workload</li> <li>□ If feasible, obtain direct numbers for prescribing provider's office and fax</li> <li>□ Discussion with payors or trend dispensing to determine which adalimumab products are preferred</li> <li>□ Order and stock adalimumab reference and biosimilar products with appropriate refrigerator space</li> <li>□ Start educating patients on reference adalimumab about the potential changes in 2023 to help mitigate nocebo effect</li> <li>□ For those who transition to adalimumab biosimilar, counsel on potential differences and ensure patients are connected to the correct financial and medication access resources as available per the manufacturer</li> <li>□ Continue to stay up to date on the adalimumab biosimilar landscape, as more products are lined up for launch and interchangeability laws may evolve</li> <li>□ Provide monitoring touchpoint at each fill to help mitigate nocebo effect</li> <li>□ Consider implementing medication safety strategies to prevent errors with dispensing (i.e. tall man lettering, standardized nomenclature for adalimumab products, storage location considerations)</li> </ul>	<ul style="list-style-type: none"> <li>□ Staff education relating to:                             <ul style="list-style-type: none"> <li>- Adalimumab biosimilar products including formulations considerations and patient resources</li> <li>- Adalimumab reference and biosimilar products prescription entry and considerations</li> <li>- Interchangeability designation as it pertains to state law</li> </ul> </li> <li>□ Update electronic health records to ensure product database for adalimumab biosimilars is up to date</li> <li>□ Review current support for benefits investigation and prior authorization services and anticipate increased demand/workload</li> <li>□ If feasible, obtain direct numbers for most commonly utilized specialty pharmacies</li> <li>□ Discussion with payors or trend dispensing to determine which adalimumab products are preferred among the most common health insurance plans seen in practice</li> <li>□ Start educating patients on reference adalimumab about the potential changes in 2023 to help mitigate nocebo effect</li> <li>□ For those who transition to adalimumab biosimilar, counsel on potential differences and ensure patients are connected to the correct financial and medication access resources as available per the manufacturer</li> <li>□ Continue to stay up to date on the adalimumab biosimilar landscape, as more products are lined up for launch and interchangeability laws may evolve</li> <li>□ Implement monitoring program post-adalimumab transition to ensure clinical stability and minimize nocebo effect</li> <li>□ Serve as the primary champion for adalimumab biosimilar and update collaborative scope of practice; continue to refine workflows and be the point person in clinic for patients relating to adalimumab biosimilar education, questions/concerns, and workflow needs</li> </ul>

and provider's office should trigger a new benefits investigation to confirm access to adalimumab therapy for each patient. Benefits investigation teams will need to carefully confirm that a new prior authorization is requested by the plan for continuation of reference adalimumab vs switching to a biosimilar. If and when a patient's plan requires switching from reference adalimumab to a biosimilar product, notifying the patient about the need for updated prior authorization is key to streamlining care and minimizing gaps in therapy. Some patients may understandably be concerned about the transition to a biosimilar and request that the insurance mandate be challenged or appealed. Given that transitioning to a biosimilar would be considered appropriate in most clinical situations, pharmacists are well positioned to provide education to patients about biosimilar products and emphasize that appealing such a decision is likely to lead to adalimumab treatment delays, which would be a detrimental course of action, as opposed to switching to a biosimilar and continuing treatment without any

interruptions. Additionally, pharmacists need to consider the financial implications of switching adalimumab products and ensure that the affordability of the biosimilar is secured via a copay savings program or patient assistance program.

Similarly, given the launch of several adalimumab biosimilar products on the market, it is possible that payors may update their formularies, subjecting patients to multiple switches to adalimumab biosimilars. Emerging data have shown no worsening of clinical outcomes or adverse effects when switching from one adalimumab product to another, but data evaluating switching among 3 or more adalimumab biosimilars are currently lacking.<sup>39</sup> Pharmacists are well positioned to stay up to date on emerging literature and provide education on such data once they are available.

**Affordability.** Biosimilars are designed to stimulate market competition and lead to lower healthcare costs due to their lower list prices compared to their reference biologic products. Unfortunately, these cost savings may not extend to the patient level

depending on the insurance copay structure or the availability of patient financial assistance programs. If a plan requires a patient to initiate or transition to an adalimumab biosimilar and an authorization for the product has been secured, the patient should be directed to the specific manufacturer of that product for financial support and resources. Pharmacists are well positioned to help patients navigate this landscape, and, if this opportunity is missed, patients may end up paying more in copays than if they were on the reference product.

Currently, a copay card is available for reference adalimumab with a robust amount of funding and patient assistance programs for uninsured or underinsured patients and those with Medicare. Potential financial considerations with the adalimumab biosimilars include a lack of patient assistance programs inclusive of Medicare patients with unaffordable copays and off-label dosing (beyond the maintenance regimen of 40 mg every 14 days). The manufacturer of reference adalimumab currently offers additional resources such as nursing