

Operational Timeline Considerations for Implementation of Biosimilar Adalimumab

As we approach the launch of the first adalimumab biosimilar, it is important for health systems to implement utilization plans for these competing products. This checklist is intended to provide guidance to engage providers, pharmacy staff, clinics, and leadership in the development of processes and protocols necessary to ease the transition to biosimilar adalimumab for your organization and the patients you serve. This checklist has been developed to guide the pharmacy team on actions necessary to begin now, at 1 month before launch of adalimumab biosimilars, and at time of launch. The timeline of actions should be based on the estimated initiation of the switch to biosimilar adalimumab for the institution or hospital likely to occur January 2023 and/or June 2023 when more products will be available.

Ambulatory Checklist

Now:

- Educate providers and clinic staff
 - Provide education on approved products and estimated launch dates
 - Engage in conversations on preference for low vs high concentration and citrate-free formulations
 - Educate and discuss interchangeability designation
 - Determine preferred option for switching to biosimilar adalimumab (Table 1)
 - New starts
 - Switch all patients
 - Wait for prior authorization renewal to switch
 - Wait for payer mandated switch
- Initiate discussion for workflow
 - Begin conversations with pharmacy team to help design workflow
 - Discuss if pharmacist will work under collaborative practice agreements for assisting with conversions
 - Discuss staffing needs for prior authorizations (PA) and patient assistance programs (PAP)
 - Medical assistants
 - Pharmacy technicians
 - Utilize health system-based specialty pharmacy services, if available
- Address any concerns from providers and clinic staff
- Assess your payers
 - Work with your managed care and finance departments to identify your top 5 payers in preparation for future and ongoing conversations around payer preference and coverage

At least 1 month before launch (December and/or May 2023):

- Decide what patients you will converting/starting on biosimilar adalimumab products
 - New starts only use biosimilar adalimumab
 - Switch all current patients on therapy to preferred product
 - Wait for prior authorizations to expire and switch at time of resubmitting new prior authorization
 - Wait for payer mandates

Table 1: Operational Pros and Cons for Transition Timelines for Biosimilar Adalimumab Conversion

	Pro	Con
New starts only to begin biosimilar	Initially a very similar process to current workflow for originator adalimumab Education occurs when adalimumab is prescribed (conversation happens up front rather than calling later)	If and when insurance mandates switch, you will need a process in place at that time
Switch all patients	Initial increase in workload up front then less through the year	Initial increase in workload Insurances may mandate originator brand or different biosimilar as they become available Will need to reach out to patient to discuss/educate on switch to biosimilar
Wait for prior authorization renewal to switch	Workload dispersed throughout the year Conversation/education on biosimilar with patient at time of refill request	Workload dispersed throughout the year Reach out to payer to find out preferred product Need to make sure patients have enough medication to get through until prior authorization and/or patient assistance is approved
Wait for payer mandated switch	Payer should notify you as to what biosimilar is preferred (this may happen when you submit refill to payer) Workload dispersed over time	Workload dispersed throughout the year Will need to reach out to patient to discuss/educate on switch to biosimilar Need to make sure patients have enough medication to get through until prior auth/possible patient assistance is approved

- Begin writing a Collaborative Practice Agreement (CPA) (if applicable) to allow pharmacist to make switch from originator to biosimilar
 - Consider including all biosimilars that are planned for launch in 2023.

- Consider allowing pharmacist to switch products based on payer preference/mandates
- Consider reaching out to major payers to gather product preference
 - What product(s) will they prefer?
 - Will they mandate change and when will this happen?
 - Partner with managed care and financial colleagues to encourage payers to adopt a parity coverage policy for biosimilars
- Consider reaching out to suppliers to gather information
 - Copay cards
 - Patient assistance programs
- Work with IT team to make sure that products will be available in the electronic medical record (EMR) and how to accurately label the different biosimilar products so that patients will receive correct product

January 2023 or after:

Once you decide on how you would like to proceed in converting patients from originator to biosimilar you should start to create a workflow.

- New start/new to medication
 - All new patients will start on a biosimilar
 - Verify which biosimilar each payer prefers
 - Once preferred biosimilar identified, workflow would be similar to current workflow for originator adalimumab (Humira)
 - Using a collaborative practice agreement, pharmacists can assist in writing new prescriptions; otherwise notify provider that patient needs new prescription
 - Reach out to patient to discuss the switch to biosimilar
- Switch all patients currently on originator adalimumab
 - Run reports for patients on low vs high concentration
 - Initially only low concentration biosimilars will be available
 - Identify patients who are candidates to switch
 - Using collaborative practice agreement, the pharmacist can assist in writing new prescriptions; otherwise notify provider that the patient needs new prescription for the biosimilar
 - Reach out to patient to discuss switch to biosimilar
 - Verify if patient is using patient assistance program
 - Verify patient will have enough medications on hand until new PA approved
 - Decide who is responsible for prior authorizations/patient assistance
 - Clinic staff responsibility
 - Specialty pharmacy team responsibility
 - Verify product covered by payer
 - Assist patients who will need to apply for copay cards/patient assistance
 - Create education resources for patients that will be switched

- Biosimilar education
 - Injection device education and training
- Create a plan for education for patients
 - Phone
 - Virtual
 - In Office visit
- Create standardized documentation for switching to biosimilar products so that patients will be prescribed biosimilar product in future
- Wait for prior authorization renewal, not yet mandated by payer
 - Refill requested by patient and payer states needs prior authorization
 - Identify if patient is candidate to switch (assess concentration, citrate-free, autoinjector vs prefilled syringe)
 - Pharmacists working under collaborative practice agreements can assist in writing new prescriptions; otherwise notify provider that patient needs new prescription
 - Reach out to patient to discuss switch to biosimilar
 - Verify if patient is using patient assistance program
 - Verify patient will have enough medication on hand until new prior authorization is approved
 - Decide who is responsible for prior authorizations/patient assistance
 - Clinic staff responsibility
 - Specialty pharmacy team responsibility
 - Verify product covered by payer
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- Wait for prior authorization, not yet mandated by payer
 - Payer mandates switch to biosimilar
 - Run report to identify patients with identified insurance that is mandating switch
 - Identify if patient is a candidate to switch (assess concentration, citrate-free, autoinjector vs prefilled syringe)
 - Pharmacists working under collaborative practice agreements can assist in writing new prescriptions; otherwise notify provider that patient needs new prescription
 - Reach out to patient to discuss switch to biosimilar
 - Verify if patient is using patient assistance program

- Verify patient will have enough medication on hand until new prior authorization is approved
- Decide who is responsible for prior authorizations/patient assistance
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To learn more, please contact
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