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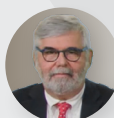
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Interchangeable Biosimilars in Inflammatory Diseases

B iologics have revolutionized the management of immune-mediated inflammatory diseases (IMIDs). Biosimilars are biologics that exhibit no significant differences in safety or efficacy compared with their reference products. Introduction of biosimilars into the IMID market can reduce costs and expand patient access to biologics. In a recent AJMC Stakeholder Summit moderated by **Ryan Haumschild, PharmD, MS, MBA**, director of pharmacy services at Emory Healthcare and the Winship Cancer Institute of Emory University in Atlanta, Georgia, a panel of experts provided an overview of the clinical, economic, and humanistic burden of inflammatory conditions in the United States. The experts examined the role of biologics, biosimilars, and interchangeable biosimilars in disease management. The panel also discussed the potential value of biosimilars to patients, payers, and providers in treating inflammatory diseases and suggested strategies to facilitate biosimilar uptake.

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BURDEN OF DISEASE

Encompassing disorders that can affect any organ system, IMIDs represent a diverse group of medical conditions characterized by acute or chronic inflammation with potentially disabling characteristics.¹ Collectively, these conditions have a prevalence of between 5% and 7% in Western society, with genetics and environmental factors influencing IMID susceptibility.^{1,2} Although these diseases share common underlying pathogenetic features, they possess distinct pathways that influence their clinical presentation, age and sex distribution, tissue localization, and response to treatments.³ Among IMIDs are rheumatoid arthritis (RA), spondyloarthritis, connective tissue disorders, inflammatory bowel disease (IBD), asthma, cutaneous inflammatory conditions such as psoriasis and atopic dermatitis, and autoimmune neurological diseases such as multiple sclerosis.³

In addition to the unique medical challenges inherent to each disease, the state of chronic inflammation often increases risk of comorbidities, such as cardiovascular disease and cancer, further affecting patients' quality of life and mortality.^{4,5} For example, an individual with RA is twice as likely to

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develop lymphoma and nearly 9 times as likely to develop interstitial lung disease.^{4,6} Moreover, increasing evidence suggests that individuals with IMIDs have higher rates of psychiatric disorders, such as depression and anxiety, compared with the general population.⁷⁻¹⁰

Humanistic and Economic Impact of Inflammatory Diseases

Conditions involving immune-mediated inflammation often cause organ damage, physical disability, and reduced work-related productivity.¹¹ Despite advancements in treatment strategies, patients with IMIDs continue

to experience a compromised health-related quality of life.¹¹

Historically, the direct costs linked to IMIDs have been largely driven by inpatient care, particularly surgeries.¹² However, with the introduction of costly biologic treatments that are highly effective in delaying or preventing the need for surgery or hospitalization, most direct costs have shifted toward drug treatments. In contrast, indirect costs encompass expenses incurred outside the health care system. Indirect costs include individual costs such as medical appointment transportation and societal costs such as employee absenteeism and reduced productivity due to disability.¹² Because IMIDs often affect individuals during their prime working years, work disability has been a primary contributor to the total costs associated with these conditions, resulting in significant financial implications for employers.¹²⁻¹⁴ The introduction of biologics for IMID treatment can improve quality of life and reduce direct and indirect costs. For example, earlier access to biologics has been shown to positively affect work ability for patients with RA.¹⁵

Biologics and Barriers to Use for the Treatment of Inflammatory Diseases

Cytokine dysregulation plays a central role in the pathophysiology of IMIDs.¹⁶ Targeting cytokines with biologic therapies has transformed treatment of IMIDs due to their efficacy, speed of onset, and tolerability.¹⁶ Anticytokine therapies that have emerged to treat various IMIDs are listed in the [Table](#)¹⁷⁻²¹ to the left.

Cost and insurance reimbursement are significant barriers to biologic use for patients and physicians.²² Once resolved, these barriers tend to reemerge over the treatment period with changes in insurance, reauthorizations, affordability, and availability of assistance programs.²²

Stakeholder Insights

Haumschild; **Maia Kayal, MD, MS**, assistant professor in the Dr Henry D. Janowitz Division of Gastroenterology at the Icahn School of Medicine at Mount Sinai and the Susan and Leonard Feinstein Inflammatory Bowel Disease Center in New York, New York; **Jonathan Kay, MD**, the Timothy S. and Elaine L. Peterson Chair in Rheumatology, professor of

TABLE. Biologic Therapies Used to Treat Various IMIDs¹⁷⁻²¹

Drug name	Target
Infliximab	
Adalimumab	
Certolizumab pegol	TNF- α
Golimumab	
Etanercept	
Vedolizumab	
Natalizumab	Integrins
Guselkumab	
Risankizumab	
Tildrakizumab	IL-23
Mirikizumab	
Ustekinumab	IL-12/IL-23
Tocilizumab	
Sarilumab	IL-6
Secukinumab	
Brodalumab	IL-17
Anakinra	IL-1
Mepolizumab	
Reslizumab	IL-5
Benralizumab	
Dupilumab	IL-4
Omalizumab	IgE
Tofacitinib	
Upadacitinib	JAK
Rituximab	
Ocrelizumab	CD20
Ofatumumab	
Abatacept	CD80/CD86
Alemtuzumab	CD52
Ozanimod	
Fingolimod	Sphingosine-1-phosphate
Siponimod	receptor

IMID, immune-mediated inflammatory disease; JAK, Janus kinase; TNF, tumor necrosis factor.



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medicine and of population and quantitative health sciences, director of clinical research in rheumatology, and the executive codirector of the MD/PhD program at UMass Chan Medical School in Worcester, Massachusetts; and **Kimberly C. Chen, DO, MSHLM**, a senior health plan executive with expertise in the Medicare and dual Medicaid-commercial markets, discussed the burden of IMIDs, addressing the medical and economic challenges associated with disease management. Kayal provided a brief overview of IMIDs, noting a possible genetic predisposition to many of these conditions. Additionally, tobacco use, obesity, and age might be associated as risk factors, although the exact risk factors for all IMIDs have not been definitively identified. Kay explained that chronic inflammation contributes to the development of comorbid conditions, highlighting atherosclerosis, lymphoma, and interstitial lung disease. Kay added that depression can manifest as reactive depression and occur as an IMID comorbidity, but the underlying pathophysiology of depression linked to inflammatory diseases remains unclear. Kayal added that disability itself is a major comorbidity for these patients, noting that in gastroenterology “we’ve been adopting...disability-related quality of life and using that as an outcome for our patients, because it’s a big deal for patients to not be able to get through the day [or] not be able to go to work or manage their personal life. I think we increasingly understand how...[IMIDs] are [affecting] disability. We’re recognizing that it’s an outcome that we need to improve upon for their lives.”

Chen discussed the humanistic burden of disease, noting that “patients with rheumatoid disease are [affected] significantly in their quality of life because of the pain, the medical treatment, surgeries they go through, and impaired function. [That] not only [affects] them but also their family and coworkers.” Chen went on to explain the direct and indirect economic impacts of IMIDs. “We all know they have a high health care cost due to...the specialty drugs...as well as surgery and inpatient care. Those are the direct costs...but some of the indirect costs...[are] a decrease in productivity at work, their coworkers significantly having to help them, as well as earlier disability and disability payment. Also, transportation, medication cost, and...the mental health impact.”

Kay reflected that “in rheumatologic diseases, disability used to be an inevitable consequence of the disease [despite] the treatments that we had, but over the past 25 years with biologics available, disability has been markedly decreased. Patients with rheumatologic diseases can now look forward to normal life and normal function and not necessarily anticipate surgical procedures. It used to be when I started in rheumatology that patients would anticipate having both hips and both knees replaced, [as well as] surgery on their hands. Nowadays a patient with [RA] treated aggressively can expect to have a normal life managed with once-weekly or biweekly medication.” Haumschild agreed, adding that “the great thing is [that] we have new therapeutics that are providing really good resolution of disease, limiting the type of progression that we’re used to with patients and...[allowing them to have] productive lives. Now the main thing we’re working on is how we control those comorbidities that lead to nonadherence or may lead to exacerbation of current symptoms and making sure that we have the right coverage—so dealing with financial toxicity, transportation vulnerability, and having a great proportion of days covered.”

Education is incredibly important when initiating treatment with a biosimilar...to educate the patient that biosimilars have been studied extensively, developed very carefully, and shown to be equivalent in efficacy and comparable in safety and immunogenicity.

Jonathan Kay, MD
UMass Chan Medical School
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Chen added that treatment for chronic inflammatory conditions has nearly doubled in the past 20 years, noting that “even though the surgical cost...went down, the pharmaceutical spending continues to increase and has become one of the highest costs for almost all the health plans as well as health care providers.” Kay elaborated that “patients typically switch insurance coverage every several years, and the insurance provider that is covering the cost of the expense of medication may not be held responsible for the cost of surgery down the road. So, the cost to the insurance provider of current medications may not mitigate savings in the future, which is an important consideration to the payers because their expenses may not be balanced by savings.” Kayal explained that unfortunately with IBD, there is a big delay in starting patients on biologics. As a result, patients often are inappropriately treated during the curative time when they are most vulnerable and then require surgeries that could have been prevented by promptly starting the biologic. Kayal concluded that “the window of opportunity to start a good drug is not happening, so they’re getting surgery, and the costs are high in that up-front phase, and they still need to go on a biologic [postoperatively].... In the United States, the community hasn’t necessarily adopted the early use of biologics...so the costs haven’t necessarily been driven down.” Chen added that in addition to biologic treatment, these unplanned emergency surgeries and multiple readmissions are drivers of medical costs.

Kay discussed economic barriers to biologic use, explaining that “the real barrier based on economics is an almost artificial barrier that’s placed by pharmacy benefit manager companies...that contract with payers to manage their formularies.... Their profit is generated both by the administrative fees that they gain from the small proportion of the list price [and the] proportion of the rebates or discounts that they keep.... The pharmacy benefit managers require prior authorization, not because they’re trying to help us determine the most appropriate medication for a patient but rather because they’re trying to align the medication that’s prescribed for the patient with the medication that will give them the best advantage in negotiating discounts and rebates.... The cost of the medication and the opportunities for pharmacy benefit managers to gain rebates and generate profits limits access to some biologics because the providers’ choice is not completely free and is dictated by the pharmacy benefit managers’ formulary.” Haumschild responded that “health plans and employer groups are [also] trying to afford the increasing cost of care related to both medical and pharmacy benefit, [whereas] pharmacy benefit

managers may just see that pharmacy piece of it. There might be true medical cost offsets if you gave a patient therapy sooner. The more we align the benefits between pharmacy and medical, [the more it is] going to create better access.”

The panel went on to discuss health inequalities that restrict access to treatment with biologics, such as transportation vulnerability and employer flexibility. Kay noted that “transportation vulnerability isn’t limited to being unable to attend an infusion center to get an infusible biologic. Transportation vulnerability often limits access to medical appointments...[which] delays or even prevents treatment of active disease.” Kayal added that access depends on “whether their employer is willing to give them time off to get the infusion [or] make it to that appointment where they learn how to use an injectable.... If a patient doesn’t have time to take off from work to come and see you in the office, or even see their therapist that day, then it’s just going to be a continuous downward spiral of the impact of the disease on their day-to-day.” Chen responded that usually patients have a case manager within the health plan who can support them with the social determinants of health (SDOH) issues, such as transportation. Chen added to “always keep in mind that collaboration between the health plan and providers is really a win-win to better support our patients, especially [those] with SDOH needs.”

IMPACT OF BIOSIMILARS ON TREATING IMIDS

Biologic agents are manufactured using cell lines to produce a specific amino acid sequence, which is subject to imprecisely defined post-translational modification.²³ As a result, biologics cannot be exactly replicated as done for generic medications.²³ Biosimilars are alternative formulations for licensed biologics that are approved based on their similarity to the reference product in terms of purity, safety, and potency.²⁴ With the Biologics Price Competition and Innovation Act of 2009, the US Congress permitted an abbreviated licensure pathway 351(k) for products that are biosimilar to biological reference products approved by the FDA.²⁴ To prove no clinically meaningful differences between the biosimilar and reference agent, extensive comparative clinical efficacy and safety assessments are performed, including structural and functional protein studies, animal studies, and clinical studies.²⁴ Required clinical studies assess biosimilar immunogenicity, pharmacokinetics, pharmacodynamics, and equivalent efficacy in at least 1 reference product indication.²⁴ With adequate scientific justification, biosimilar data can be extrapolated and approved for all

indications held by the reference product without comparative clinical studies for each indication.²⁴

Given their generally lower acquisition costs compared with the reference product, biosimilars have introduced price competition into the market, resulting in reduced treatment expenses for patients.¹⁴ Health authorities have increasingly embraced biosimilars as they aim to reduce health care spending on biologics and use cost savings to enhance patient access to these highly effective medications.¹⁴ Shifting to biosimilar use may lead to improved disease management and a reduction in long-term complications, benefiting the overall health economy and ensuring optimal treatment for all patients.¹⁴ To date, more than 10 biologics have served as reference products for approval of more than 30 biosimilars.²⁵

An approved biosimilar can be designated as “interchangeable” by the FDA, meaning the biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.²⁶ Interchangeability is based on additional clinical data evaluating whether repeated switching between a reference product and its biosimilar affects clinical performance or leads to differences in its pharmacokinetics or immunogenicity.²⁶ Switching studies are designed to assess whether one product will affect the immune response to the other based on theoretical concerns and experience with switching between different biologics that are not biosimilar.²⁷

In the past decade, biosimilars for infliximab, followed by etanercept and eventually adalimumab, have been granted approval for treating IMIDs.¹⁴ The launches of biosimilars for adalimumab and etanercept were on hold in the United States due to patent litigation agreements.²⁵ In Europe, introduction of these biosimilars to the market has resulted in economic benefits attributed to lower biosimilar prices and reductions in reference product prices in response to the competition posed by biosimilars.¹⁴ These short-term cost savings and expanded patient access could also translate into long-term savings by treating patients with biologics at an earlier disease stage, which could potentially delay or prevent costly hospitalizations and surgical interventions.¹⁴

Stakeholder Insights

IMPACT OF BIOSIMILARS AND CHALLENGES FOR BIOSIMILAR UPTAKE

Kay explained that “a biosimilar is a copy of a biopharmaceutical. It’s not a generic because generics are small molecules, where the active ingredient can be reproduced exactly, but the biosimilar, being a complex protein, is not an exact copy. [The biosimilar] is shown in an extensive development process to be equivalent in its efficacy and comparable in its safety to the reference product.” Chen went on to discuss the potential for biosimilars to lower costs compared with the reference products, noting that “on average, new medication will take minimally greater than 10 years, and the development costs [are more than] \$2.6 billion. [However], biosimilars take approximately 5 to 9 years and are only [approximately] \$100 million.... In 2020, the research showed that biosimilars have saved nearly \$1 billion and in 2022, they have projected a savings of [more than] \$30 billion. If we continue the use of biosimilars, there’s a potential savings of \$183 billion in the next 5 years.” Haumschild added that there is great opportunity

...If you have the data to support that the biosimilar is essentially very similar to the reference products in terms of pharmacodynamics and immunogenicity and safety, then it makes sense to approve across clinical indications of the reference product.

Maia Kayal, MD, MS
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for biosimilars to decrease the cost of care and still provide high value as their adoption has in Europe.

From a provider perspective, Kayal expressed excitement around approval of biosimilars for IMiD treatments, highlighting the approval of multiple adalimumab biosimilars this year. Kayal added that “for patients starting off with severe disease that can only progress...you... want to start the biologic up front. Cost was a big inhibitor of that and now with the biosimilars at a lower cost they [can] afford, we’re able to start the right drug earlier for our patients and really prevent the disease severity progressing along.”

Kay discussed some of the challenges for the adoption of biosimilars in the United States, noting that “the biggest challenge is that the patient needs to share in the savings. A patient accepting a biosimilar, which is equivalent in effectiveness and comparable in safety, is not giving up anything...but to make that change for the sake of saving the payer...[or] pharmacy benefit manager money, and not sharing in those cost savings, really doesn’t make sense. The success of biosimilars is dependent on including the patient in the economic advantage of the biosimilars.” Kay indicated that the nocebo effect may also contribute to challenges in patient adoption of biosimilars, citing open-label, nonmandatory switching studies that demonstrated the importance of patient education to avoid biosimilar discontinuation for subjective reasons, such as a patient’s perception of lower efficacy.^{28,29} Kay concluded that “education is incredibly important when initiating treatment with a biosimilar...to educate the patient that biosimilars have been studied extensively, developed very carefully, and shown to be equivalent in efficacy and comparable in safety and immunogenicity.” Kay added that providers may struggle with educating the patient adequately about biosimilars while addressing all their medical needs in the brief time allotted for their appointment.

Kayal agreed, adding that spending time on education is imperative, especially with the injectable biosimilars, which may be formulated, packaged, or injected differently. Kayal summarized that “taking that time up front to understand what the patient’s perspective is on switching to a biosimilar, allay their concerns, and then understand even on a deeper level which biosimilar will be prescribed, what [it] looks like, [and] how...they can use [it]—[that] is really key to get them to buy into the idea of a biosimilar.”

Kay added that there may be differences regarding patient uptake of infusible vs injectable biosimilars. Patients may not notice much change with the infusion or associated adverse effects. In contrast, auto-injectors are proprietary to the manufacturer of the reference product, so the patient will notice that the biosimilar auto-injector is different. However, Kay noted that the auto-injector is an opportunity for the biosimilar manufacturer to differentiate the biosimilar and gain a competitive advantage over the reference product. Additional differentiating factors could be needle gauge and inclusion of citrate buffer in the formulation.

Haumschild and Kay discussed additional provider challenges regarding restricted payer coverage that may not allow dispensing at internal specialty pharmacies. Haumschild cited a study from his institution that measured better adherence to medication filled at the internal health system specialty pharmacy vs an external specialty pharmacy.³⁰ Kay agreed and asserted, “I would use this platform to advocate

Patients with rheumatoid disease are [affected] significantly in their quality of life because of the pain, the medical treatment, surgeries they go through, and impaired function. [That] not only [affects] them but also their family and coworkers.

Kimberly C. Chen, DO, MSHLM
Senior Health Plan Executive

to payers to be more liberal in supporting specialty pharmacies and allowing institutional specialty pharmacies to dispense these medications, because so much of the direct involvement of the pharmacy liaison with the patient and the provider is important in [adherence]. And [adherence], to the payer, is going to result in less [cost] in the way of comorbidities and consequences of inadequately treated disease.”

Chen noted that challenges for biosimilar uptake from a payer perspective are to ensure that providers and patients are educated, supported, and incentivized to facilitate biosimilar utilization. Regarding specific steps payers can take to support the adoption of biosimilars, Chen explained that providers in rural areas may need to be educated about biosimilars. She also suggested sending a home health care nurse to help patients with biosimilar injection, even if their initial health plan does not cover such services. Additionally, working to include biosimilars in the formulary is another vital step in promoting their adoption.

Kayal indicated that it is appropriate to extrapolate clinical data across multiple indications in the biosimilar setting because there is no significant clinical difference in terms of safety and efficacy between the biosimilar and the reference product. Kayal added that “if the reason that we’re pursuing this road of biosimilars is to reduce costs, get more drugs into the patient’s hands, [and] reduce the time to approve a new agent and the cost that’s associated with that approval... if you have the data to support that the biosimilar is essentially very similar to the reference products in terms of pharmacodynamics and immunogenicity and safety, then it makes sense to approve across clinical indications of the reference product.”

Kay discussed the current landscape of adalimumab biosimilars, noting that 9 adalimumab biosimilars have been approved by the FDA as of June 19, 2023. He noted that the adalimumab biosimilars are characterized by different formulations, including low or high concentrations and citrate-free or citrate-containing buffers. Kay added that all the adalimumab biosimilars are accompanied by patient assistance programs, similar to those offered for the adalimumab reference product, and he explained that the adalimumab biosimilars faced delays in reaching the US market due to patent litigation with AbbVie. The biosimilar manufacturers reached agreements with AbbVie to pay royalties for intellectual property rights and have since been releasing their biosimilars to the market on prespecified dates in 2023.

INTERCHANGEABLE BIOSIMILARS

Kayal defined an interchangeable biosimilar as one that can be substituted for the reference product without intervention by the prescribing

health care provider. She explained that the manufacturer takes extra steps to definitively prove to the FDA that there is no clinically meaningful difference in safety and efficacy compared with the reference product through a switching study. Kayal elaborated that a switching study compares outcomes for patients staying on the reference product and those who switch between the reference product and biosimilar, and she concluded that “having that designation doesn’t necessarily mean that this biosimilar is better, more efficacious, or more safe. It just means that the FDA had the data provided by the manufacturer through a switching study to prove definitively that there was no difference in the outcomes.”

Kay noted that the first adalimumab biosimilar to have the interchangeable designation is Boehringer Ingelheim’s self-administered adalimumab biosimilar, based on a switching study conducted in plaque psoriasis. Additionally, interchangeable data for Pfizer’s self-administered adalimumab biosimilar in RA are being reviewed by the FDA.

Kayal emphasized the importance of provider education to introduce interchangeable biosimilars, which will lead to greater uptake, explaining that many busy providers may not be aware of the currently approved biosimilars and which ones have interchangeability status. “I’m not confident that many of our providers know necessarily that biosimilars have the same safety and efficacy profiles as the reference product...,” she said. “Figuring out a way to educate providers before [we] even educate patients is key, because they’re the ones [who] are going to be sending that message and relaying it along.” Kayal explained that education should include the biosimilars that are currently available and their specific characteristics. Chen suggested supplying providers and their support staff with patient-friendly educational materials.

From a payer perspective, Chen noted that pharmacists can be instrumental in increasing the utilization of generic drugs, and they should be leveraged to support integration of the biosimilar. Chen explained that by implementing the interchangeability for the biosimilar, there is a significant decrease in the medical cost and improvement in accessibility for the patient. Chen added that “in the US, there are only 2 health care systems that [have] mandatory interchangeability, which are the [Veterans Affairs system and] Kaiser Permanente. Just by implementing that interchangeability, they have an improvement of 80% of adherence compared with an average of 3.2%.”

Kayal said that every state in the United States has its own interchangeability laws, and the challenge is understanding these laws and how they affect patient access. She added that states will likely require interchangeability only if it economically benefits the patient, noting that “this adds another layer of challenges [for] the pharmacist, because

they have to understand each patient’s managed care landscape, their plan’s formularies, [and] whether this is increasing the patient’s out-of-pocket cost.... Understanding each state’s variability is key for the pharmacist and the provider.”

Haumschild asked Kay to outline any clinical concerns with automatic substitution for biosimilars built into electronic health records, to which Kay responded, “I don’t have any [clinical concerns related to automatic substitution at the pharmacy for an interchangeable biosimilar]. A biosimilar that has been reviewed and approved by the FDA has been shown to be equivalent in efficacy and comparable in safety to its reference product.”

Kay explained that there is no difference in adverse effects between an FDA-approved biosimilar and the reference product, and there should be an economic advantage to the patient. Kay added that “the ideal biosimilar incentive would be for the pharmacy benefit management company...to eliminate prior authorization as a requirement for the biosimilar, [but] to continue to require it for the reference product for the patient. The co-payment should be waived for a biosimilar but should still be there for the reference product.” Kay emphasized that “biosimilars must survive, as...they induce market competition and put a brake on the inevitable and inexorable rise in cost of reference products over time.” Chen agreed that payers can tier biosimilars with more favorable benefits, such as no co-pay or a fixed reimbursement for the patient.

Chen emphasized that automatic substitution of biosimilars is beneficial for all parties involved. By eliminating the administrative burden of prior authorization, patients can gain improved accessibility and more timely access to these drugs. Moreover, shifting toward biosimilars can result in overall cost savings, making biologics more affordable and increasing market competitiveness. Kay responded that automatic substitution may not be desired for pharmacy benefit managers in the way they are currently structured, noting that reform is needed.

Kayal perceives that payers are eager to incorporate interchangeable biosimilars into their formularies because they are translating into cost savings. Kay responded that introduction of infusible infliximab biosimilars has reduced the cost of the reference product by approximately 50% compared with 2017, when the first infliximab biosimilar was released, so that now the reference product is comparably priced. Kay concluded that “biosimilars introduce price competition that drives the cost down, not only of the biosimilars but also the reference product, thereby contributing to the savings for the health care system.”

FUTURE CONSIDERATIONS AND UNMET NEEDS

Maximizing the potential benefits of biosimilars to deliver cost savings and improved patient access requires effective cooperation of all stakeholders.³¹ Payers should provide education and incentivize patients and providers to increase utilization of biosimilars.³¹ Physicians should enhance their overall understanding of biosimilars and familiarize themselves with their specific characteristics to confidently prescribe and sufficiently prepare patients for the transition.³¹ Patients and physicians should recognize the potential for nocebo effects when

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using biosimilars.³¹ Biosimilar developers should minimize costs to competitively price their products and consider additional innovation to differentiate their product among multiple approved biosimilars.³¹ With stakeholder collaboration for facilitating biosimilar utilization, the continued clinical benefits of biologic therapy can be sustained within the health care system.³¹

Stakeholder Insights

Kay reiterated that biosimilars introduce price competition, which reduces the cost of all medications within the class and prevents the inexorable rise in the cost of biopharmaceuticals that occurs with no biosimilars available. Interchangeable biosimilars can be substituted by the pharmacist if a prescription is written for the reference product, which will help to ensure biosimilar use and sustain their existence to keep prices of biopharmaceuticals in check. Haumschild agreed, noting that “the sustainability [and] economic impacts are clear.... If we can roll out [biosimilars]...it’s going to benefit our patients and providers a lot, [and] our health care spending as a whole.”

Kayal expressed excitement for biosimilars in the IMID field, especially in managing IBD, where the introduction of interchangeable biosimilars may facilitate earlier access to medication for patients. Kayal explained that introduction of biosimilars is “important for these [IMIDs] because they’re all chronic, they’re all progressive, [and] they all...get worse over time. If we can start [biologic therapy] early...and do it in a way that is less burdensome for the patient and the payer by using an interchangeable biosimilar or biosimilar...then we’re actually mitigating that disease early on. We’re [also] reducing costs over time, because we’re reducing the disability, the comorbidities, the need for surgery and hospitalizations, and...at the end of the day, just significantly improving our patients’ lives.”

Chen concluded with payer strategies to ameliorate the high health care costs stemming from specialty drugs, including “having provider [and] patient education...about the biosimilars...mandating switch interchangeability, and [trying] to use biosimilars as a new start when it’s appropriate. Then lastly, incentivizing patients or health care providers to increase utilization of biosimilars.” •

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