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Interchangeable biosimilars: A new era in healthcare system

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Abstract

An important development in the area of biologic drugs, interchangeable biosimilars have possible advantages in terms of accessibility and affordability. Like generic medications are handled, these items are described as biosimilars that can be replaced for the reference biologic without the necessity of physician involvement. To earn this interchangeable designation, the U.S. Food and Drug Administration (FDA) has set particular criteria for a biosimilar which include proving that it is highly similar to the reference product, producing the same clinical outcome in any patient, and ensuring that switching between the two does not pose greater risks than using the reference product alone. Exchangeability requires robust clinical studies, especially those that evaluate the safety and effectiveness of switching biosimilars and reference counterparts. The "three-switch" concept involves patients switching between the reference medicine and the interchangeable biosimilar numerous times. Despite these strict restrictions, interchangeable biosimilars' reduced prices might improve patient access to key biologics, particularly for chronic disorders like autoimmune diseases and malignancies. However, issues exist regarding provider and patient acceptability of these solutions. Concerns over safety, effectiveness, and the ramifications of switching have contributed to reticence in their acceptance. This is especially obvious in therapeutic areas when patients remain stable on their existing therapy. Regulatory frameworks at both federal and state levels also impact how interchangeable biosimilars are employed in reality, with various legislation altering replacement procedures.

In summary, although interchangeable biosimilars have potential for improving healthcare cost and accessibility, continued efforts are required to resolve concerns around their usage and to speed regulatory procedures to ease their adoption in clinical settings.

Keywords: Biologics; Biosimilars; Interchangeable; Substitution

1. Introduction

A biologic or organic product is a training made from dwelling entities, which includes human, animal, yeast, or microbes, and includes drugs and vaccines composed of proteins, carbohydrates, nucleic acids, or mixtures of those components. This huge class additionally encompasses cells and tissues utilized in transplantation [1]. Biosimilars aren't specific replicas of the brand-call biologic product however are proven to be especially comparable. Due to the complex nature of biologics, both in composition and manufacturing tactics, this intrinsic variability poses demanding situations for regulatory approval [2]. Biologics are commonly larger in length than chemical medicines, making their manufacturing and purification greater complicated and high-priced as compared to traditional chemical pharmaceuticals. This has been stated by way of the FDA and the pharmaceutical enterprise in addressing the herbal versions in organic products [3].

Biosimilars are biologics that closely resemble the reference drug, and there are no significant clinical differences in purity, safety, or efficacy. They act as an alternative to the original biologic replacement [4]. Although biosimilars can

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be compared to generic drugs because they provide clinically equivalent alternatives, there are important differences. Unlike generic drug equivalents, biosimilars are synthesized by biological systems, resulting in some inherent differences in their protein structure [5]. Biosimilars incorporate natural processes in their preparation, resulting in small changes in protein molecules. This is in contrast to chemical compounds, which are usually composed of chemical compounds and have a consistent molecular structure [6].

Biosimilars are approved based on substantial similarity to the reference biologic, show no clinically relevant differences in safety or efficacy. This ensures that biosimilars can be considered equivalent substitutes for their reference products [7]. The introduction of biosimilars increases availability of biopharmaceuticals, increases therapeutic availability to healthcare providers and patients and creates competition in the market, which can lead to lower prices [8]. Unlike molecules smaller, biology is studied in living systems, contributing to natural diversity. This difference indicates that biosimilars cannot be effectively evaluated against another batch of the same reference product. Thus, analysis of biosimilars requires that the results remain within specified margins of accuracy to ensure safe conversion of the biosimilar and reference organic [9]. Currently, all biosimilars are administered by infusion or injection. Most people with rheumatoid arthritis and Crohn's disease are given a dose every eight weeks. The formulation and frequency of infliximab-diab is similar to the baseline drug and is intended to be used under the supervision of a healthcare professional and as a result practitioners can be called upon to prescribe biosimilar therapy more frequently [10].

2. Interchangeability

A biosimilar can be recognized as a "substitution" under the United States (US) Biologics Price Competition and Innovation Act (BPCIA), which allows a registered healthcare provider as a pharmacy to substitute the reference drug for manufacture the reference product. Substitutions are allowed. In fact, in most countries, if a biosimilar is interchangeable, it can be used instead of the reference [11]. Similar benefits and risks can be considered in relation to a biosimilar product that is consistent with regulatory standards for biosimilars, whether or not substitution is indicated

To comply with the new designation of exchanges in the US (as defined by the BPCIA), "an applicant must provide sufficient information to demonstrate biosimilarity and that the biological product can be expected to produce the same therapeutic outcome as a drug administered to a patient," adding that "if the biological product is administered more than once, the risk of decreased safety or efficacy of the biological product and the modification or alteration of the representation does not outweigh the risk of using the reference product without such modification or alteration" [12].

A drug may be swapped for another with the same therapeutic effect thanks to a product quality known as interchangeability. There are many techniques of interchanging. While (automatic) substitution is the practice of dispensing one medicine instead of another equivalent and inter changeable medicine at the pharmacy level without consulting the prescriber, switching is the decision made by the prescriber to replace one medicine with another with the same therapeutic intent [13].

Apart from being a biosimilar, an interchangeable product needs satisfy further criteria depending on a particular "switch trial design," claims the US FDA. Section 351(k) of the BLA details interchangeability requirements. Apart from demonstrating bio-similarity to the reference product, the rules specify that the risk of safety (including immunogenicity) or reduced efficacy of alternating or switching between the biosimilar and the reference product should not be higher than the risk of using the reference product by itself. Unlike the EMA, which says that there is 'no reason to believe that harmful immunogenicity should be expected following repeated switching; the FDA considers that the risk of increased immunogenicity following repeated switching to be a key concern when establishing interchange ability [14].

According to FDA guidelines, hospital transfer studies should examine immunosuppression and be analyzed descriptively as a secondary outcome. We agree that a descriptive study of the immune system is appropriate because, despite the fact that there is currently no accepted distinction associated with changes in the immune system of clinical significance, it cannot provide a meaningful comparison between drugs with lower anti-drug antibody (ADA) concentrations. We believe that the main emphasis in interchangeability studies should be on the development of immunogenicity profiles in biosimilars and comparable reference products due to interchangeability. given the limited experience with biosimilar polyswitches, there is a regulatory expectation that more switch studies will be performed to support the exchangeability designation [15]. However, since similarities between the biosimilar and the reference have already been observed, it is expected that once the patients are sorted between the biosimilar and the reference, their immune responses will be compared to patients with psoriasis. Switching between Amgevita® (Amgen Europe

B.V., Breda, The Netherlands) and a reference drug (Humira®) showed that switching between treatments did not affect the immune response [16].

Single or repeated switches between originators and biosimilars did not have a detrimental effect on effectiveness, safety, or immunogenicity, according to analysis of EPAR-included switch data, in keeping with previous evaluations on clinical switch trials. There were no unanticipated safety concerns or documented loss of effectiveness at a frequency higher than would be expected from the reference product [17].

Food and Drug Administration guidelines state that "although endpoint efficacy studies may be helpful, the results of many clinical efforts in terms of treatment rates will be sensitive to large variations in supply use or in the immune system only for longer-term studies and cannot be checked with a large number of switches" [18].

First insulin to reach interchangeable biosimilar certification is Semglee® (insulin glargine-yfgn; Viatris [previously Mylan] Morgantown, West Virginia). The interchangeable name for the reference insulin might suggest advantages over other generic biosimilar drugs. This might also encourage more general biosimilars' producers to pursue the interchangeable designation in order to stay competitive [19].

3. Advantages of Interchangeable Biosimilars

- Cost-effectiveness: Interchangeable biosimilars are generally less expensive than original biologics. This can result in significant cost savings for health plans, insurance companies, and patients. When interchangeable biosimilars are released, competition increases, possibly reducing the costs of biosimilars and native biologics [20].
- Improved Access to treatment: Lower prices may make high-quality biological medicines more accessible to a larger patient population, especially for disorders requiring costly biologic treatments like cancer or autoimmune diseases. Pharmacists may replace an interchangeable biosimilar for its reference medicine without having consent from the prescribing physician, making it simpler for patients to get medication [21].
- Clinical Efficacy and Safety: Interchangeable biosimilars go through thorough testing by means of regulatory bodies (e.g., FDA, EMA) to guarantee they may be as safe and effective because the authentic biologic. These biosimilars must exhibit no giant clinical variations in phrases of effectiveness and protection compared to their reference biologic [22].
- Reduced treatment waste: Patients can transition between the original biologic and an interchangeable biosimilar without experiencing significant changes in treatment outcome, reducing the need for continuous medical care throughout the transition [23].

4. Disadvantages of Interchangeable Biosimilars

- Possible immunological issues: Although uncommon, some individuals might also expand immune responses to biosimilars that were no longer present with the original biologic, imparting a treatment were effective or have terrible consequences [24].
- Patient and company hesitation: Some healthcare experts and patients can be reluctant to interchange from depended on biologics to biosimilars due to issues approximately capacity interactions with because of its incompatibility, even though the biosimilars had been shown to be clinically comparable. Despite regulatory approval, biosimilars are perceived through a few patients as inferior or much less powerful, affecting remedy adherence [25].
- Complex Manufacturing: Biosimilars are more complicated to produce than small-molecule generic pharmaceuticals, resulting to changes across manufacturing batches, which may result in discrepancies in effectiveness or safety. The intricacy of biosimilar manufacture and regulatory regulations may cause to supply chain delays, making constant availability a difficulty [26].
- Regulatory and Legal Barriers: The regulatory licensing procedure for interchangeable biosimilars may be long and expensive, which can delay their arrival to the market. Ongoing patent disputes between original biologic makers and biosimilar companies might further delay down the availability of biosimilars [27].

Limited Data in Certain Populations: While biosimilars are extensively studied, long-term data in certain populations, such as pediatric or elderly patients, could be restricted relative to the original biologic, raising ambiguity in some therapeutic situations [28].

5. Market Value of Interchangeable Biosimilars

As interchangeable biosimilars become more accepted and used in the healthcare system, their market value grows. The U.S. biosimilars business, which has been increasing, is expected to rise significantly in future years. As of early 2023, overall expenditure on biosimilars in the United States was about $1.9 billion, with an expected increase to $5 billion by 2027. Biosimilars for popular biologics, such as Humira, are driving market expansion [29]. Currently, ten FDA-approved interchangeable biosimilars, including Abrilada and Cyltezo, may be replaced for reference drugs without a doctor's prescription, possibly enhancing patient access and lowering costs. Despite adoption problems, especially in specific therapeutic categories like insulin, the general prognosis is encouraging, with predicted competition resulting in reduced pricing and more availability of these treatments [30].

6. Scope Of Interchangeable Biosimilars:

The enlargement of interchangeable biosimilars is growing rapidly because the pharmaceutical enterprise seeks to improve patient get entry to biologics while lowering healthcare expenses. Here are some highlights in their scope:

- Industry Growth: Biosimilars enterprise trade is predicted to develop unexpectedly. The market is anticipated to reach $5 billion via 2027 due to the expected growth in FDA approvals and the want to replace cost-powerful organic alternatives with options will increase therefore [31].
- Therapeutic Areas: Interchangeable biosimilars are being developed for numerous packages along with the remedy of autoimmune diseases, most cancers and diabetes. There were eight FDA-authorized interchangeable biosimilars with the aid of March 2024, and extra are probable to be brought. This includes biosimilars of relatively admired biologics inclusive of adalimumab and insulin glargine [32].
- Regulatory Environment: The regulatory environment for interchangeable biosimilars has changed, facilitating their improvement and market front. The FDA's interchangeability guiding principle permits pharmacists to update these medicinal drugs for reference biologics without contacting the doctor, therefore growing accessibility [33].
- Patient Accessibility: Interchangeable biosimilars might also drastically increase affected person get right of entry to essential prescribed drugs with the aid of making remedy alternatives extra inexpensive. This is mainly vital in controlling continual illnesses that want long-term treatment [34].
- Economic Impact: By improving competition in the biologics marketplace, interchangeable biosimilars have the ability to reduce healthcare fees for both sufferers and the machine. Savings from those items may lessen economic pressures, making biologic drug treatments extra on hand [35].

7. List of Approved Interchangeable Biosimilars

Table 1 List of Approved Interchangeable Biosimilars

Interchangeable Biosimilars	Reference Product	Approval Date
Cyltezo	Humira (adalimumab-adbm)	October 2021
Abrilada	Humira (adalimumab-afzb)	November 2019
Semglee	Lantus (Insulin glargine-yfgn)	July 2021
Cimerli	Lucentis (ranibizumab-eqrn)	August 2022
Rezvoglar	Lantus (Insulin glargine-aglr)	November 2022
Byooviz	Lucentis (ranibizumab-nuna)	October 2023
Wezlana	Stelara (Ustekinumab-auub)	October 2023
Simlandi	Humira (adalimumab-ryvk)	February 2024
Jubbonti	Prolia (denosumab-bbdz)	March 2024
Wyost	Xgena (denosumab-bbdz)	March 2024

7.1. Cyltezo

Cyltezo (adalimumab-adbm) is a biosimilar to Humira (adalimumab), and was approved by the FDA as the first interchangeable monoclonal antibody biosimilar in 2021. This clearance allows Humira to be substituted for Cyltezo without the need for modification prescription drugs, and can increase availability, reduce availability and there is a cost. Cyltezo is licensed to treat a variety of conditions including rheumatoid arthritis, Crohn's disease, psoriatic arthritis, and ulcerative colitis [36]. The clinical trials that led to its approval showed Cyltezo to be very comparable to Humira in terms of safety, strength and pharmacokinetics. A 48-week study comparing the ACR20 found similar efficacy in terms of response rate and safety profile. A comparative study of Humira and Cyltezo found no significant differences in immunogenicity or safety [37].

7.2. Mechanism

TNF-α is a key inflammatory factor in autoimmune illnesses such as rheumatoid arthritis, Crohn's disease, and psoriatic arthritis. Cyltezo inhibits TNF-α from interacting with receptors on cell surfaces, thereby lowering inflammation. By neutralizing TNF-α, which over activates the immune system, Cyltezo reduces inflammation, tissue damage, and discomfort associated with these autoimmune illnesses. This action helps to alleviate symptoms and decrease the progression of various conditions [38].

7.3. Abrilada

Abrilada (adalimumab-afzb) is a biosimilar of Humira (adalimumab) this is certified for the treatment of a lot of persistent inflammatory conditions. These situations encompass rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's ailment, ulcerative colitis, and plaque psoriasis. As a biosimilar, Abrilada is intended to have the equal effectiveness, safety, and medical outcomes as Humira but at a probably lower price [39]. Abrilada objectives TNF-α, a molecule implicated in systemic infection. By lowering TNF-α's interaction with cellular surface receptors, Abrilada decreases infection and the immunological responses related to autoimmune disorders. The FDA approved Abrilada after rigorous medical investigations, which include the REFLECTIONS B538-02 study, which determined no sizable variations among Abrilada and Humira in phrases of effectiveness, protection, and immunogenicity. This biosimilar offers a decrease-value opportunity to Humira while keeping the identical healing advantages [40].

7.4. Mechanism

Abrilada is a monoclonal antibody that targets only TNF-α. In conditions such as rheumatoid arthritis, Crohn's disease, and psoriatic arthritis, this activity prevents TNF-α from binding to cell surface receptors, thus triggering inflammation and immune responses Abrilada inhibits TNF -α pathway and reduces tissue damage and inflammation caused by an overactive immune system. This system helps control symptoms such as injury, inflammation and joint discomfort in autoimmune diseases. Inhibition of TNF-α also attenuates inflammatory diseases, thereby reducing tissue damage and improving patients' quality of life [41].

7.5. Semglee

Semglee is an FDA-approved biosimilar and interchangeable product for insulin glargine (Lantus), that's used to treat each kind 1 and kind 2 diabetes. Semglee, the first interchangeable biosimilar insulin in the United States, provides a greater value-effective opportunity to Lantus while keeping comparable effectiveness and protection [42].

Semglee and Lantus have not shown any appreciable variations in A1C decline, insulin dosage, or hypoglycemia danger, so they might be a suitable substitute for Lantus in diabetes treatment. One of Semglee's main gifts is its ability to help diabetes patients pay less for treatment. Semglee is plenty much less costly than Lantus, making it more reachable to folks who may additionally battle to have enough money insulin. Furthermore, Semglee can be replaced at the drugstore without the requirement for a prescription, permitting patients to attain the biosimilar more easily. Clinicians and patients need to be knowledgeable of the regulation and other available options [43].

7.6. Mechanism

Semglee's reference product, like Lantus, is a modified version of human insulin. This change causes the epidermis to shed, resulting in microcrystals upon injection. These crystals slowly release less insulin into the bloodstream over time. Once synthesized, insulin glargine binds to the insulin receptors of muscle and fat cells, allowing glucose to be absorbed from the circulation and used for energy It also reduces hepatic glucose synthesis, preventing release excess glucose is not absorbed into the bloodstream, especially during fasting [44].

7.7. Rezvoglar

Rezvoglar is a biosimilar of insulin glargine (Lantus) that got authorized via the FDA as the second interchangeable insulin. It is a protracted-appearing human insulin analog that improves glycemic manage in adults and pediatric patients with type 1 diabetes, further to adults with type 2 diabetes [45]. Rezvoglar, like Lantus, is brought as soon as an afternoon through subcutaneous injection. The dosage is custom designed to the affected person's demands, and it isn't recommended for diabetic ketoacidosis or hypoglycemic episodes. Following royal tips, Rezvoglar, an interchangeable biosimilar, can be modified for Lantus at the drugstore stage without prior permission from the prescribing medical doctor. This class offers for greater versatile treatment alternatives and strives to limit prices for patients with the assist of imparting a less high-priced opportunity to Lantus. Rezvoglar, like different insulin glargine treatments, can also explain undesirable results which includes hypoglycemia, fluid retention, weight advantage, and injection internet site responses [46].

7.8. Mechanism

Rezvoglar produces microcrystals in the subcutaneous tissue after injection, progressively liberating insulin glargine into the movement over 24 hours. This keeps a constant, "basal" level of insulin, simulating the pancreas' slow and consistent insulin secretion. Once in the flow, insulin glargine binds to insulin receptors on muscle and fat cells, allowing glucose to be absorbed from the blood and stored in these tissues. This lowers blood glucose ranges by encouraging the garage or use of glucose for power. Insulin glargine additionally decreases glucose synthesis within the liver, limiting immoderate glucose release, specially between meals and in a single day [47].

7.9. Byooviz

Byooviz was authorized as the first biosimilar of Lucentis. It was licensed to treat neovascular (wet) age-related macular degeneration, a significant cause of vision loss and blindness for Americans over the age of 65. It is also licensed to treat macular edema after retinal vein occlusion (blockage of veins in the retina) and myopic choroidal neovascularization, a vision-threatening consequence of myopia (near-sightedness). Byooviz is now both biosimilar to and interchangeable with the reference product, demonstrating that there is no unanticipated risk in terms of safety or diminished efficacy [48]. The ranibizumab biosimilar Byooviz from Samsung Bioepis has now obtained interchangeability status, placing it on par with Cimerli, which was initially authorized as an interchangeable biosimilar in August 2022. Byooviz is a biosimilar product of Lucentis, which is sold by Novartis and Roche, and it was authorized as the first ophthalmology biosimilar in the United States in September 2021. The biosimilar is now interchangeable with Lucentis for the treatment of neovascular age-related macular degeneration, macular edema after retinal vein blockage, and myopic choroidal neovascularization [49].

7.10. Mechanism

Byooviz (ranibizumab-nuna) is a biosimilar of Lucentis (ranibizumab) and is used to treat numerous eye disorders, including wet age-related macular degeneration (AMD), diabetic macular edema (DME), and retinal vein occlusion (RVO). Its mode of action includes blocking vascular endothelial growth factor A (VEGF-A), a protein involved in encouraging the formation of aberrant blood vessels in the eye. By inhibiting VEGF-A, Byooviz stops the creation of these aberrant arteries and decreases vascular permeability, thus limiting leakage and minimizing the swelling and damage in the retina that may contribute to vision loss in these circumstances [50].

7.11. Wezlana

Wezlana (ustekinumab-auub) is a biosimilar of Stelara, a well-known medicine used to treat autoimmune disorders such as Crohn's disease, ulcerative colitis, plaque psoriasis, and psoriatic arthritis. Approved by the FDA in 2023, Wezlana is categorized as an "interchangeable" biosimilar, meaning it may be swapped for Stelara without requiring the prescriber’s clearance. This is crucial because it can provide a more cost-effective option if it becomes accessible, potentially by early 2025 [51]. Like Stelara, Wezlana acts by targeting and inhibiting interleukins IL-12 and IL-23, which are implicated in the inflammatory processes of these illnesses. Its approval followed trials that revealed no significant difference in effectiveness or safety compared to Stelara [52].

7.12. Mechanism

Wezlana (ustekinumab-auub) functions via the same mode of action as Stelara (ustekinumab), targeting particular cytokines implicated in immune response and inflammation. It binds to the p40 subunit of two important interleukins, IL-12 and IL-23, which play a role in the inflammatory pathways of autoimmune diseases. By inhibiting these cytokines, Wezlana affects the signaling essential for the activation of specific immune cells, notably T-cells, that contribute to chronic inflammation. This suppression lowers the immune response in disorders such as plaque psoriasis, Crohn's

disease, ulcerative colitis, and psoriatic arthritis. The decrease in inflammation helps to manage the symptoms and course of many illnesses by controlling the hyperactive immune response [53].

7.13. Simlandi

Simlandi is biosimilar to adalimumab, which is used to treat several chronic inflammatory diseases including rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis and works through tumor necrosis factor-alpha (TNF-α), an inflammatory protein in the body reducing inflammation. By reducing TNF-α, Simlandi helps reduce inflammation and associated symptoms, improving patient outcomes in many diseases. This is licensed as a high-potency, citrate-free formulation, which reduces injection site pain and allows for more efficient drug delivery protocols, requiring fewer additional injections in addition to Simlandi classified as interchangeable with Humira, i.e. A swap without additional recipes can be done, making it more accessible to patients and less expensive [54].

7.14. Mechanism

Simlandi (Adalimumab-Rivk) combines the same activity as Adalimumab, the booster component of Humira. This is a monoclonal antibody that primarily prefers and binds to tumor necrosis element-alpha (TNF-α), which is a pro-inflammatory cytokine associated with the frame of the immune response TNF-α has a key in influencing the in inflammatory processes of autoimmune diseases a Rheumatoid arthritis, Crohn's disease, and rheumatoid arthritis are included. By reducing TNF-α, Simlandi prevents cells from attaching to their downstream receptors, thus reducing contamination, immune tissue damage, and reducing signs and symptoms associated with chronic inflammatory events [55].

7.15. Jubbonti

Jubbonti is a biosimilar to denosumab, which is approved interchangeably with Prolia, a drug used to treat osteoporosis and other bone diseases. Jubbonti works by targeting the RANKL protein, which plays a key role in bone resorption. RANKL promotes cellular and osteoblast breakdown. By binding to RANKL, Jubbonti inhibits this activity and reduces osteoclast production and function, thereby reducing bone destruction. The technique helps treat diseases such as postmenopausal osteoporosis, hormone therapy-related bone loss in patients with cancer, and glucocorticoid-induced osteoporosis. Jubbonti is for the treatment of at-risk populations greater to fracture, due to osteoporosis or others including prostate cancer in bone related diseases, also licensed to improve bone density in men and women following long-term glucocorticoid treatment of a cancer [56]. Warnings associated with Jubbonti include the risk of severe hypocalcemia, especially in individuals with advanced kidney disease, and the possibility of bone fractures in the jaw, nonspecific hip fractures and diseases.

7.16. Mechanism

Jubbonti (denosumab-bbdz) works by targeting and suppressing RANKL (receptor activator of nuclear factor kappa-B ligand), a critical protein that affects the creation, activity, and survival of osteoclasts—cells responsible for breaking down bone. RANKL binds to its receptor, RANK, on the surface of osteoclasts and their progenitors, resulting in bone resorption (breakdown). By binding to RANKL with high specificity and affinity, Jubbonti blocks this interaction, hence lowering osteoclast activity and delaying bone resorption. This process helps cure disorders including osteoporosis and bone loss linked with hormone therapy in cancer patients, by conserving bone density and minimizing the risk of fractures. It is especially advantageous in postmenopausal women, males receiving prostate cancer treatment, and patients on long-term glucocorticoid medication, all of whom are at increased risk of bone loss.

7.17. Wyost

Wyost is the first interchangeable biosimilar licensed to prevent bone-related consequences of cancer, including fracture, requirement for radiation to the bone, or spinal cord compression. Wyost® is approved to prevent skeletal-related events (SREs) in patients with multiple myeloma and in patients with bone metastases from solid tumors [57]. It is also indicated to treat adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Additionally, Wyost is used to treat hypercalcemia of malignancy refractory to bisphosphonate therapy.

7.18. Mechanism

Wyost is a biosimilar of denosumab, especially to Xgeva, which is intended to avoid bone problems in individuals with advanced cancer affecting bone and to treat adults and skeletally mature adolescents with giant cell tumor of bone [58]. The method of action for Wyost, like denosumab, includes binding to and blocking RANKL (Receptor Activator of Nuclear factor Kappa-B Ligand), a crucial factor in the creation, function, and survival of osteoclasts. By decreasing

RANKL, Wyost stops osteoclasts from breaking down bone tissue, hence lowering bone loss and limiting skeletal-related events (SREs) including fractures in cancer patients with bone metastasis. This inhibition also helps control disorders such as giant cell tumors of bone by lowering the activity of osteoclast-like giant cells, which are common in this kind of tumor.

8. Conclusion

Biosimilars are the growing benefits in healthcare, especially in making biologics more accessible and affordable. Interchangeable biosimilars must meet high regulatory standards in order to be used to interchange reference biologics without affecting safety, efficacy, or quality. The ability to substitute at the pharmacy provides patients with improved access to key medications and reduces healthcare costs. However, education is needed for health professionals to build confidence in its use and acceptance of its utility in treatment protocols.

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