Patient-Centered Biosimilars Communications Policies

Recommendations For Specialty Pharmacies

As biosimilars become increasingly available, specialty pharmacies are in a powerful position to influence patient attitudes. Our organizations believe patient confidence in biosimilars is critical to avoid a negative patient experience or adverse impacts like the "nocebo effect" in which a patient has a negative health outcome out of a belief that the drug they took was lesser. It is therefore in every stakeholder's best interest to prioritize proactive education and communication processes that meaningfully address patient questions and concerns, and we believe every health care stakeholder has a distinct responsibility in communicating with patients.

Below please find specific recommendations for patient communications, based on patient data from our organizations.

Ensure patient communications about any switch to a biosimilar occur in advance of the patient receiving the new medication.

1. 85% of those surveyed would want to know if they were receiving a biosimilar in place of their biologic, and importantly, when asked what they would do if they received a different medication in the mail without any advance notification, many patients indicated they would assume it is the wrong medication and call their pharmacist or PBM and/or not take the medication. To avoid this, we recommend specialty pharmacists proactively communicate with patients for whom they are initiating a substitution of a biosimilar, particularly an interchangeable for which the pharmacist may be the only point of contact to the patient about a substitution. Communications should include:
    - Specifics about what the switch is and where they can find more information about the product
    - Specific information about the product such as if it is citrate-free and if it has a different injection device, in addition to how to learn to use the new medication
    - Information about training and assistance on using the new product, to the extent the injection device or aspects of the product are different
    - Offer to answer any additional questions via the patient's preferred communication platform
2. Communicate with patients through multiple methods if possible, such as patient portals, email, text, and written mail. Our surveys show email as the top preferred source of information, followed by patient portals and written mail, though focus group respondents overwhelmingly believed stakeholders should utilize multiple methods of communication.

Use FDA recommendations and language as a model in external and patient-facing materials. Specific recommendations include:

1. Avoid using the term "reference product" and instead use "brand" or "original." In a 2022 Arthritis Foundation (AF) survey, 65% of patients had not heard the term "reference product."
2. Clearly define the term "biosimilars" in patient-friendly language, such as "a biosimilar is a type of biologic used to treat certain forms of arthritis, Crohn's disease, ulcerative colitis, psoriasis and psoriatic arthritis. They are FDA approved as having no clinically-meaningful difference from the original brand drug." 49% of AF survey respondents had never heard the term "biosimilar," and only 21% had a good understanding of biosimilars.
3. Link to the FDA's patient education resources in each patient communication.

Highlight safety and clinical efficacy data in communications about biosimilars.

1. Safety risks, treatment efficacy and side effects are types of information of most interest to patients; patient communications should provide information and links for specific data on these topics.
2. Communications should include a combination of information about clinical safety and effectiveness and stories from other patients who have switched to biosimilars.
3. 67% of AF survey respondents would be open to using a biosimilar if they had more information; however, only 23% would be comfortable using one with what they know right now.

Ensure that any communications include links to educational resources or toll-free helplines provided by national patient organizations.

1. Patient organizations can provide information to patients in addition to connecting them with trained experts and other patients. We encourage specialty pharmacies to include links such as:
    a. Arthritis Foundation Helpline and biosimilars landing page
    b. National Psoriasis Foundation Patient Navigation Center and biosimilars landing page
    c. Crohn's & Colitis Foundation IBD Help Center and biosimilars landing page.

Tailor messaging for different scenarios, e.g., patients who have never used a reference biologic

1. AF survey data showed biologic-naïve patients were more concerned with side effects (91%), how often the medication would be taken (69%), and how the medication is taken (79%), in addition to overall comparisons to other types of treatments (64%).
2. Biologic experienced patients were significantly more concerned with specific details around making the switch to biosimilars than biologic naïve patients. Emphasizing safety and efficacy data is particularly important for those switching directly from the reference product (86%). Real world data about switches is significantly more important to biologic experienced patients than those who are biologic naïve (53% vs 45%).

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