AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

Empowering rheumatology professionals to excel in their specialty

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February 18, 2021

Pramod John, Ph.D.
CEO
VIVIO Health, Inc.
1933 Davis Street, Ste. 274
San Leandro, CA 94577

Dear Dr. John:

The American College of Rheumatology (ACR) is a national organization representing rheumatologists, health professionals, and scientists that advances rheumatology through education, research, patient advocacy, and practice support. Our organization fosters excellence in the care of people with arthritis and rheumatic and musculoskeletal diseases. The ACR is the largest professional organization of rheumatologists in the United States with over 7,700 rheumatologists and rheumatology health professionals.

The ACR has recently received numerous complaints regarding VIVIO's interference with the treatment of rheumatology patients and we request a call with VIVIO leadership to further discuss these concerns. An overview of the major complaints we've received is included below. Also enclosed for your review are several ACR position statements regarding the treatment of Rheumatic Disease.

Coverage for Biologic Drugs and Non-Medical Switching

The ACR is aware that VIVIO has instructed rheumatology practices to switch patients from one biologic drug to another and/or to the biosimilar version of a drug with cost being the sole consideration. We strongly oppose forced, non-medical switching and urge VIVIO to revisit these decisions. While the ACR shares your concerns about the high cost of biologic drugs, forcing stable patients to switch from their current therapy is not an acceptable solution. Forced switching needlessly puts patients at risk for significant long-term consequences including irreversible joint damage, organ damage, missed work, additional healthcare utilization and disability. For many patients the journey to finding an effective treatment has already involved numerous treatment failures. Force switching a patient who has finally reached low disease activity or remission simply due to cost containment is a most egregious violation of the patient's welfare and runs counter to all treatment guidelines. The ACR strongly believes that coverage policies should be based on the best interests of the patient and the available peer reviewed literature. When a health plan or benefits manager mandates a formulary change, patients who are well controlled on stable therapy should be allowed to "grandfather" their treatment at no additional cost.

Biologic drugs are vitally important therapeutic options for patients with rheumatic diseases. These drugs are highly effective and have the potential to reduce long-term disability. The decision to choose one biologic over another requires careful clinical evaluation and

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consideration by a physician and patient. Factors such as an individual patient's age, gender, diagnosis, medications, specific organ manifestations, antibody status, disease severity, comorbid conditions, and ability to tolerate the route of administration strongly influence the specific biologic choice. The complex medical decision making, and subsequent risks associated with these medications, fall on the physician and patient; these decisions should not be curtailed by health plan coverage policies.

The ACR shares your interest in the role of biosimilars in promoting cost savings but they must be used in the appropriate clinical context. Transitions from different versions of the same molecule must be undertaken with caution and with informed patient consent. Biosimilar products are not generics but rather very similar versions of the original product. Biologic drugs are very large molecules created by using the machinery of a living cell and the complex nature of protein production makes it impossible to produce identical molecules. Thus, the biosimilar drug is not the same. Non-medical switching of any product carries risk of disease flare to the patient and is unacceptable.

Biologic Taper Program

The ACR is aware that your company has informed certain rheumatology practices their patient(s) may be eligible for VIVIO's "biologic taper program" overseen by VIVIO staff. We respectfully request full details concerning this program and who is making decisions on drug dosing and frequency (including their medical credentials, licensure in the state where the affected patient resides and practice background). We would also inquire which patients this applies to, an explanation of your legal reasoning of this practice of medicine, and the name of the malpractice carrier for your organization and said provider. To be clear, we view this action as an affront to rheumatologists' clinical decision making and an egregious violation of the doctor-patient relationship. The claim that a health plan or benefits manager can initiate and direct "safe" biologic tapering is inappropriate and poses enormous risk for patients. Numerous studies suggest that tapering patients in remission off successful biologic therapy is usually not successful and threatens the health of the patient.

The use of VECTRA also deserves further discussion. While VECTRA is a potentially useful lab marker, its use in guiding clinical decisions is not endorsed by clinical guidelines, and we believe VIVIO is misunderstanding the role that a lab test can play in replacing clinical judgement, patient interview, and physical exam.

Specialty Pharmacy Acquisition and Site of Service for Infusions

The ACR is alarmed by VIVIO's directive that infusion drugs must be obtained through your specialty pharmacy. This change threatens patient access and adds to the high level of administrative burden practices face.

Practices engaging in the current buy-and-bill model operate under thin margins. For those in private clinics, the assertions we have seen in VIVIO's literature are false. Providers are paid a contracted fee for drugs which is usually minimally above acquisition cost and is much more

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transparent and cost effective than the opaque rebate based PBM model. The costs of rent and utilities for the infusion space, drug storage, insurance, and administrative time to acquire drugs, precludes most of our members and many of their local hospitals, from accepting white bagging.

An infusion patient is best cared for under the direct guidance and oversight of their rheumatologist. The ACR opposes policies that force patients to receive biologic infusions at home or in unsupervised infusion centers because such policies, designed for the sole purpose of cutting costs, undermine patient safety. Biologic drugs carry a significant risk for adverse reactions. These drugs should be administered in a monitored health care setting with onsite supervision by a provider with appropriate training in biologic infusions.

Limiting Access to FDA-Approved Treatments

The VIVIO website states: "VIVIO uses data to understand what specialty drugs do at the individual, not population level. The company's carveout product, VIVIO Precision Care™ fixes big unsolved healthcare problems: expensive drug therapies that don't work; lack of real-world effectiveness; doctors not knowing what they think they know." While the description of this product sounds precise and scientific, we are concerned by the lack of transparency, especially where it results in non-medical switching to the drug that can be acquired cheapest. Additionally, several ACR members have received letters from VIVIO which purport to place your "proprietary algorithm" above the FDA in determining treatment coverage. Suggesting that the FDA does not sufficiently assess treatment effectiveness is both dangerous and objectionable. Patients should not be denied access to a medically necessary, FDA-approved treatment due to potential cost savings for the health plan.

Conclusions

We appreciate and share your concerns about the price of biologic drugs. However, solutions to lower costs must prioritize patient access and safety. The ACR is deeply concerned that VIVIO's policies are solely focused on cost, with little regard for patients' health or quality of life.
We would greatly appreciate the opportunity to speak to you further about these issues and our concerns. To arrange a mutually convenient time for a conference call, please contact Meredith Strozier, ACR Director of Practice Advocacy, at mstrozier@rheumatology.org or (404) 633-3777.

Sincerely,

Chris Phillips, MD
Chair, ACR Insurance Subcommittee