May 5, 2021

Tunde Sotunde, MD, MBA, FAAP
President and CEO
Blue Cross and Blue Shield of North Carolina
P.O. Box 2291
Durham, NC 27702

Re: Gout Medication Coverage Policies

Dr. Sotunde,

On behalf of the undersigned organizations representing patients and providers in the gout community, we are writing to voice our concerns regarding Blue Cross Blue Shield North Carolina's (BCBS NC) coverage policies for pegloticase, an infused therapy for patients with chronic refractory gout. We are concerned that BCBS NC's Corporate Medical Policy, which restricts access to pegloticase, is overly burdensome and has a negative impact on the health outcomes of North Carolinians living with this debilitating condition.

Gout – which affects 9.2 million people in the U.S.[1] – leads to swollen joints and sudden, intensely painful attacks that can be debilitating for those living with the disease. Gout is a serious medical condition that, left untreated, can result in more frequent or enduring attacks. It can also increase patient risk for other medical conditions like kidney disease, cardiovascular disease, diabetes and stroke. Successful gout treatment is critical in maintaining patients' quality of life and their ability to work and participate in daily activities. Barriers that limit access to treatment options are inappropriate.

It has come to our attention that BCBS NC's coverage requirements for pegloticase, an FDA-approved infusion therapy for gout, require onerous step therapy protocols that are resulting in limited and delayed access for patients. Specifically, we are concerned that the requirement that patients try and fail three agents – allopurinol, febuxostat, and a uricosuric agent like probenecid – prior to accessing pegloticase is overly restrictive for patients with severe, uncontrolled gout. Requiring that patients have a clinical contraindication or intolerance to all three agents in order to bypass those steps not only poses challenges for patients, particularly those who are living with limited kidney function, but will also exacerbate existing disparities in kidney and gout care, and will almost certainly result in increased healthcare costs. With each medication failure or contraindication, patients will likely seek medical service or relief for a resulting flare, adverse side effect, or disease progression. Any cost savings acquired through delaying coverage of pegloticase is short term, and will likely be overcome by future expenditures on medical care or hospitalizations due to undermanaged gout.[2]

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[1] Michael Chen-Xu et al., "Contemporary Prevalence of Gout and Hyperuricemia in the United States and Decadal Trends: The National Health and Nutrition Examination Survey, 2007–2016," *Arthritis & Rheumatology* 71, no. 6 (2019): 991–99, https://doi.org/doi:10.1002/art.40807.

[2] Cole, M. et al. Patients with undermanaged RA have higher medical costs than other RA patients. Avalere. 2020. Access at:
https://avalere.com/insightscs/patients-with-undermanaged-ra-have-higher-medicare-costs-than-other-ra-patient

We appreciate that traditional therapies for gout, such as allopurinol, have demonstrated effectiveness for many patients. We also recognize allopurinol as an appropriate first-line treatment. However, the three required step edits are not appropriate for all patients.

We are particularly concerned about BCBS NC's requirement that patients try and fail – or demonstrate clinical contraindication or intolerance to – a uricosuric. According to estimates, between 47 and 54 percent of gout patients also live with chronic kidney disease, and gout patients not yet affected face increased risk of kidney disease.[3] Uricosuric medication comes with adverse renal effects like risk of kidney stones. Therefore, requiring gout patients, who already face kidney risks, to either fail first or demonstrate contraindication or intolerance prior to accessing their prescribed therapy serves as an inappropriate barrier. Further, a provider prescribing this treatment is already uncommon. Recent research shows that probenecid use is increasingly rare, accounting for only 5 percent of prescriptions in 2009 and decreasing to just 1 percent of gout prescriptions by 2019.[4]

For patients with gout, the road to medical stability can be challenging, and access to the appropriate treatment is critical. Gout is debilitating and progressive. Left untreated or undertreated, it can lead to increased attacks, development of uric acid deposits in the joints and throughout the body, and increased risks of other serious conditions that may result in increased healthcare usage and potential hospitalization. Preserving a clear, timely path for patients to access the gout therapy their health care provider believes most appropriate is paramount in ensuring successful disease management.

Sound coverage policies balance patient health outcomes and access to treatments with cost and safety. The best means to accomplish this balance is through policies that preserve clinician decision-making and ensure timely access to appropriate medication. On behalf of the undersigned organizations, including a number of kidney disease stakeholders, we urge you to revise this coverage policy **to ensure patients have a clear and less restrictive path to accessing infused gout therapy.**

Thank you for the opportunity to provide comment and we appreciate your attention to this matter. If we can provide further details or be of assistance, please contact Josie Cooper at jcooper@allianceforpatientaccess.org and Kindyl Boyer at kindyl.boyer@patientaccess.org.

Sincerely,

Alliance for Gout Awareness
Alliance for Patient Access
American Association of Kidney Patients
American Kidney Fund

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[3] Abdellatif AA, Elkhalili N. Management of gouty arthritis in patients with chronic kidney disease. Am J Ther. 2014 Nov-Dec;21(6):523-34. doi: 10.1097/MJT.0b013e318250f83d. PMID: 22960848.

[4] Kim, Seoyoung C et al. "Trends in Utilization of Urate-Lowering Therapies Following the US Food and Drug Administration's Boxed Warning on Febuxostat." *Arthritis & rheumatology (Hoboken, N.J.)* vol. 73,3 (2021): 542-543. doi:10.1002/art.41550

American Podiatric Medical Association
Ayafusion Wellness Clinic
Biotek Remedys
Cape Fear Arthritis Care, PLLC
Dr. Baak Arthritis Center
Global Healthy Living Foundation
Gout Education Society
The Gout Support Group of America
Infusacare Medical Services, PC
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MPP Infusion Centers
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NC Foot & Ankle Society
North Carolina Rheumatology Association
National Organization of Rheumatology Management
Premier HealthCare Associates, Inc.
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Rheumatology Nurses Society