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October 10, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard,
Baltimore, MD 21244-1850

Re: Request to Revise Medically Unlikely Edit (MUE) for J1602 (golimumab) to 400 Units

Dear Administrator Brooks-LaSure,

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

Today, ***we write to request a revision to the Medically Unlikely Edit (MUE) for J1602 (golimumab) from 300 units to 400 units.*** This change is necessary to ensure that patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis, particularly those who are obese, can receive the appropriate doses of this weight-based therapy without experiencing delays in care and administrative barriers caused by claim denials and appeals.

Background

Golimumab is dosed based on patient weight at 2 mg/kg. For patients weighing over 150 kg (330 lbs), a dose exceeding the current MUE of 300 units is required.

Given the high prevalence of obesity among patients with RA, PsA, and ankylosing spondylitis, among other autoimmune diseases, it is increasingly common for these patients to need doses that *exceed* the current MUE limit. Indeed, the inability to fully treat the chronic inflammation and control the disease process associated with these diseases adds more inflammation to an already inflammatory overload associated with obesity and metabolic syndrome, increasing a person's risk for cardiovascular disease and other disease processes associated with chronic inflammation.

Unfortunately, rheumatologists that administer golimumab to these patients are finding themselves in one of two situations: 1) either they face claim denials that must be appealed in order to be reimbursed for their costs, adding to the financial strain and administrative burden on physician practices, or 2) they must give a dose that is inappropriately low based on FDA recommendations, delaying evidence-based treatment for individuals who already experience significant disability and health challenges.

Health Equity

Further, we believe this situation raises concerns about health equity. Obesity is increasing common among patients with autoimmune diseases, such as RA, PsA, and ankylosing spondylitis, and it often compounds their disability and limits their ability to exercise or manage weight through lifestyle changes. By maintaining an MUE that does not account for the needs of this patient population, the system inadvertently creates a barrier to care for beneficiaries who are already more vulnerable.

In fact, maintaining this edit could be perceived as a violation of Section 1557 of the Affordable Care Act (ACA), which extends protection to individuals with obesity in healthcare programs and activities, provided that their obesity qualifies as a disability under federal standards. At 45 CFR § 92.207(b)(2), HHS specifically states that a covered entity – *which would include the Medicare program* – cannot have practices that deny, limit, or restrict coverage based on a protected characteristic. This could be interpreted to apply to payment edits or other mechanisms that disproportionately affect certain groups, such as obesity when it qualifies as a disability.

Request

We believe that adjusting the MUE to 400 units will help ensure that all beneficiaries may access to the care they need without unnecessary administrative barriers. Such a revision would promote equitable treatment and reduce the administrative burden on healthcare providers who must regularly file appeals for medically necessary doses beyond the current MUE.

For the reasons highlighted above, ***CSRO requests that CMS revise the MUE for J1602 to 400 units to reflect the clinical realities of dosing in beneficiaries with obesity and ensure fair and timely access to treatment for all.***

Thank you for considering our concerns on this important issue to rheumatologists and their patients. Please do not hesitate to contact us at info@csro.info should you require additional information.

Sincerely,

Coalition of State Rheumatology Organizations

References

1. Tylutka, A., et al. (2023). Assessment of metabolic syndrome predictors in relation to inflammation and visceral fat tissue in older adults. *Sci Rep* 13, 89. <https://doi.org/10.1038/s41598-022-27269-6>
2. Crowson, C. S., et al. (2013). Obesity in patients with rheumatoid arthritis: Prevalence, disease characteristics, and relationship to cardiovascular comorbidity. *Arthritis Care & Research*, 65(12), 1970-1976. <https://doi.org/10.1002/acr.22056>
3. Ajeganova, S., et al. (2015). Obesity is associated with worse outcomes in established rheumatoid arthritis: Results from the QUEST-RA study. *Annals of the Rheumatic Diseases*, 74(2), 435-441. <https://doi.org/10.1136/annrheumdis-2013-204021>

4. Jensen, M. D., et al. (2016). Obesity and the rheumatic disease patient. *The Journal of Clinical Rheumatology*, 22(6), 309-315. <https://doi.org/10.1097/RHU.0000000000000421>
5. Gremese, E., & Tulusso, B. (2014). Obesity and rheumatoid arthritis: Risk and impact on disease progression. *Journal of Rheumatology*, 41(4), 563-568. <https://doi.org/10.3899/jrheum.130945>
6. Choy, E. H., et al. (2019). Obesity and rheumatoid arthritis: Impact on occurrence, disease activity and response to therapy. *Rheumatology*, 58(2), 213-220. <https://doi.org/10.1093/rheumatology/key286>
7. Perry, S. J., et al. (2021). Prevalence of obesity and its impact on disease outcomes in rheumatoid arthritis: A systematic review and meta-analysis. *Rheumatology*, 60(3), 1006-1016. <https://doi.org/10.1093/rheumatology/keaa599>
8. Singh, S., et al. (2019). Association of obesity with RA outcomes in the U.S.: Data from a large observational cohort. *Arthritis Care & Research*, 71(12), 1606-1613. <https://doi.org/10.1002/acr.23867>