AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

Empowering rheumatology professionals to excel in their specialty

2200 Lake Boulevard NE, Atlanta, GA 30319
Phone: (404) 633-3777 • Fax (404) 633-1870 • www.rheumatology.org

Guiding Principles from the American College of Rheumatology for Scarce Resource Allocation During the COVID-19 Pandemic: IL-6 inhibition
Updated August 26, 2021

Background

Monoclonal antibodies that inhibit IL-6 through binding to the IL-6 receptor (tocilizumab and sarilumab) are routinely used by rheumatology providers in the treatment of a variety of rheumatologic conditions including rheumatoid arthritis, giant cell arteritis, juvenile idiopathic arthritis, and systemic sclerosis related interstitial lung disease. These therapies are critical to help control inflammation and to prevent long term morbidity and mortality in patients suffering from inflammatory disease. Many patients on these therapies have tenuous disease control and loss of access to treatment could be life-threatening.

COVID-19 is associated with systemic inflammation and can demonstrate heightened cytokine release and a hyperinflammatory response.(1) In June of 2021, the FDA issued an Emergency Use Authorization (EUA) for tocilizumab in hospitalized patients with Covid-19.(2) Approximately seven weeks later, Genentech reported supply shortages of intravenous (IV) tocilizumab and warned of episodic shortages in the future.(3) This shortage not only affects those afflicted with COVID-19 but also thousands of patients treated with IV tocilizumab.

We offer the following recommendations regarding the allocation of IV tocilizumab.

Recommendations

- Every effort must be made to ensure an adequate supply of IV tocilizumab. Efforts to increase production and distribution for rheumatology patients, as well as patients with COVID-19 should be supported. Protections on the supply of tocilizumab should include all aspects of the supply chain from manufacturer to wholesaler, wholesaler to pharmacy, and final distribution to patients.

- Adequate supplies of tocilizumab should be allocated for patients with rheumatologic conditions, especially those in whom drug holidays would be reasonably expected to cause a flare of their disease or require a switch to an alternative regimen that is less efficacious, less safe or unproven.

- When the IV formulation of tocilizumab is not available, we support the substitution of the subcutaneous form in place of the IV formulation with no increased cost to the patient.

2200 Lake Boulevard NE, Atlanta, GA 30319
Phone: (404) 633-3777 • Fax (404) 633-1870 • www.rheumatology.org

- In the unfortunate situation where a treatment regimen must be altered due to a shortage, every effort should be made to provide treatment with a similar mechanism of action. When drug supplies are replenished, resumption of the original treatment given by the same original delivery mechanism should be made efficient and without additional utilization management.

- During drug shortages we urge insurers to exempt rheumatology patients from prior authorization, step therapy protocols, and other utilization management practices so that they may more readily gain access to appropriate alternatives as determined by their rheumatologist or rheumatology health professional.

References:

1. Wang Z, Yang B, Li Q, Wen L, Zhang R. Clinical Features of 69 Cases With Coronavirus Disease 2019 in Wuhan, China. Clin Infect Dis. 2020 Jul 28;71(15):769-777. doi: 10.1093/cid/ciaa272. PMID: 32176772; PMCID: PMC7184452.
2. Emergency Use Authorization, FDA. Accessed August 23, 2021. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
3. https://www.gene.com/media/statements/ps_081621. Accessed August 23, 2021