

New Advances in the Treatment of Lupus: Clinical and Economic Implications for Managed Care

Systemic lupus erythematosus (SLE) is a complicated, chronic, multisystem disease that mainly affects young adults, especially women. Cumulatively, its sporadic bursts of activity can do irreparable damage to bodily organs. Tracking the epidemiology of SLE is problematic because the diagnosis is often elusive, and SLE cases are difficult to review systematically because sufferers take various routes through the healthcare provider system.

Compared with Caucasians, SLE disproportionately afflicts African-Americans, and there is evidence that it is also more prevalent among Hispanics, Asians, and Native Americans.

The course of SLE can be chronic, relapsing, or remitting, and current means of assessing its progression are

very inadequate. The corticosteroid prednisone is used to treat the serious musculoskeletal, renal, cardiovascular, and ophthalmic effects of the disease.

Lack of knowledge of the cause of SLE has thus far hindered a fully integrated approach to recognizing and managing it. Ongoing research to uncover a relationship between the endocrine system and the immune system in SLE patients gives investigators a chance to refocus their areas of inquiry. Long-awaited new treatments for SLE may well include modulation of specific hormones, such as the peptide hormone prolactin.

It has been 40 years since there have been any new developments in the treatment of SLE, and current disease management strategies result in a 70% 20-year survival rate. It is hoped that emerging

Update: Status of Prasterone*

In September 2000 a New Drug Application (NDA) was submitted by Genelabs/Watson for its lupus treatment, prasterone. The NDA was granted fast-track status in October 2000. On June 26, 2001 the Food and Drug Administration (FDA) issued a "not approvable" letter, primarily because of interpretation issues concerning efficacy and safety data that were submitted in the NDA. The FDA's Arthritis Advisory Committee did, however, agree the product demonstrated modest efficacy in women with mild-to-moderate systemic lupus erythematosus. At the time this supplement went to press, Genelabs was planning to meet with the FDA for further discussions.

**The Pink Sheet*. Chevy Chase, MD: F-D-C Reports, Inc; July 2, 2001.

immunomodulating therapies, including a synthetic form of dehydroepiandrosterone (prasterone), will lessen the need for steroid treatment among mildly afflicted patients, thereby reducing the morbidity and costs associated with the side effects of steroid use. In addition, new treatments for more severe SLE seem to be forthcoming, and improvements are being made to traditional therapies, which may be beneficial to SLE sufferers.

To fully understand the effect of SLE on a patient's quality of life, cost analyses are needed that examine the impairment

in physical functioning and the undesirable changes in appearance that result from SLE, as well as the damage caused by the accumulation of steroids in the body.

This supplement to *The American Journal of Managed Care* presents the proceedings of a symposium convened in Washington, DC on March 15 and 16, 2001. The purpose of the meeting was to share information on the epidemiology, treatment, prognosis, and economic impact of SLE.