NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

Health Technology Appraisal

Prasterone for systemic lupus erythematosus

Draft scope

Objective: To appraise the clinical and cost effectiveness of prasterone for systemic lupus erythematosus and to provide guidance to the NHS in England and Wales.[1]

Background: Systemic lupus erythematosus (SLE) is a chronic, autoimmune, inflammatory disease that may affect the skin and joints, as well as internal organs and serous membranes. SLE may begin abruptly with fever, simulating acute infection, or may develop insidiously over months or years with episodes of fever and malaise.

SLE has an estimated prevalence of 28 per 100,000 in the adult population. When extrapolated over England and Wales it gives and estimated patient group of 10500. The prevalence in various ethnic groups differs dramatically from that of the general population reaching approximately 206 per 100.000 in Afro-Caribbean women. SLE is 8 to 10 times more common in women than in men and mainly affects women in their childbearing years.

The clinical manifestations of SLE are variable. However, approximately 90% of people present with painful joints and 75% present with skin rashes such as butterfly erythema. Clinical renal involvement occurs in approximately 40% of cases. Other clinical features are, amongst others, extreme tiredness, respiratory and cardiac problems, neuropsychiatric signs and symptoms, and haematological distortions. The current 10-year survival rate is estimated to be 80-85%.

Although the aetiology of SLE is largely unknown, hormonal influences seem to play a key role in disease development and progression. Clinical measurement of disease activity in SLE involves an assessment of either the presence or absence of the characteristic signs and symptoms of disease and the results of laboratory parameters.

Current treatment options include the use of aspirin and non-steroidal anti-inflammatory drugs (NSAIDs), antimalarials, corticosteroids and immunosuppressive agents.

The technology: Prasterone (Anastar™-Genelabs) (also know as: Aslera™, Prestara™, GL701 or DHEA), is the oral generic designation of

[1] The Department of Health remit to the Institute is "To appraise the clinical and cost effectiveness of prasterone in its licensed indications for systemic lupus erythematosus".

dehydroepiandrosterone (DHEA), which is produced naturally by the adrenal glands. Patients with SLE generally have abnormally low levels of DHEA. Prasterone works by replacing DHEA. Prasterone is also being trialed for its ability to reduce corticorsteroid use and minimise bone loss associated with steroid use in people with SLE.

NICE is currently awaiting the wording of the marketing authorisation for the use of prasterone to treat SLE.

Intervention(s)	Prasterone (Anastar) within its marketing authorisation(s).
Population(s)	People with systemic lupus erythematosus.
Current standard treatments (comparators)	Management of systemic lupus erythematosus without prasterone
Other considerations	Outcomes should include: • **Survival** • **Disease activity (including flares)** • **Damage (either disease-induced or therapy induced)** - Adverse effects of treatment - Decreasing corticosteroid requirements and protection against corticosteroid-induced osteoporosis • **Health related quality of life** - Measures of pain, functioning and/or well-being - Including an assessment of fatigue Cost effectiveness of treatments should ideally be expressed in terms of incremental cost per quality adjusted life year. The Institute seeks the views of the consultees on the following: • How severity of SLE is graded. • How disease activity is routinely measured. • How flares are defined. • Appropriate sub-groups to be considered