NewTherapiesSubgroup

GMMMG Greater Manchester Medicines Management Group

NHS

**24th January 2012**

# Belimumab (Benlysta®) for Systemic lupus erythematosus (SLE)



**The Interface Prescribing & New Therapies Subgroup discussed the above drug at a meeting on the 24th January 2012 The recommendation of this subgroup is as follows:***

The Interface Prescribing and New Therapies Subgroup of the GMMMG considered the use of Belimumab (Benlysta®) for Systemic lupus erythematosus (SLE)

**The group recommends that belimumab may be used as per the treatment algorithm attached.**

Initiation of belimumab should be restricted to tertiary specialist clinicians; this may involve direct initiation or the advice to initiate following assessment of patient after referral.

Discontinuation of belimumab should be considered if there is no improvement in disease control (as per protocol) after 6 months of treatment. If belimumab is given in patients who would have normally received rituximab then it is likely that there would be no additional costs[1] for this patient group.

The group noted that a NICE TA on belimumab will be published in May 2012.

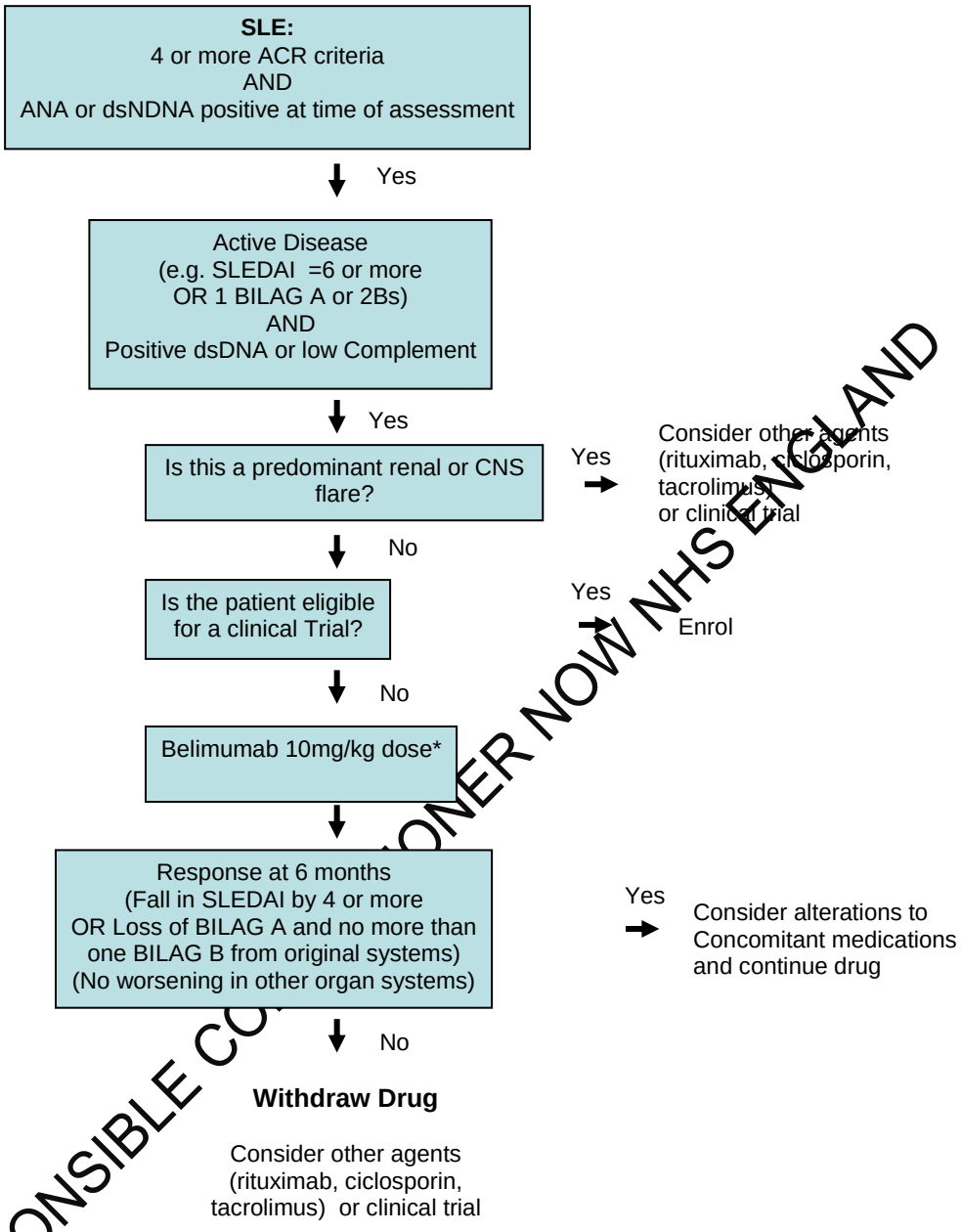
According to set criteria belimumab was deemed to be a medium priority for funding.

[1]Belimumab is priced at £121.50 for a 120mg vial and £405 for a 400mg vial. Costs may vary in different settings because of negotiated procurement discounts

**Review Date: January 2014**

* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.
▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.

# Belimumab in SLE - Treatment Algorithm
# (Supplied by CMFT)






*see Appendix for Warnings, Precautions and Pregnancy

**Appendix to Treatment Algorithm: Warnings, Precautions and Pregnancy**

**Limitations of Use**

The efficacy of Belimumab has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. BELIMUMAB has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of BELIMUMAB is not recommended in these situations.

**CONTRAINDICATION**
BELIMUMAB is contraindicated in patients who have had anaphylaxis with belimumab

**Serious Infections**
- Serious and sometimes fatal infections have been reported in patients receiving immunosuppressive agents, including BELIMUMAB
- Caution should be exercised when considering use in patients with a history of chronic infections
- Patients receiving therapy for a chronic infection should not receive BELIMUMAB
- Consider interrupting BELIMUMAB therapy in patients who develop a new infection while receiving BELIMUMAB

**Depression**
- In clinical trials, psychiatric events (primarily depression, insomnia, and anxiety) were reported more frequently with BELIMUMAB than with placebo
- Serious psychiatric events, serious depression, and two suicides were also reported
- It is unknown if BELIMUMAB treatment is associated with increased risk for these events
- Instruct patients to contact their healthcare provider if they experience new or worsening depression, suicidal thoughts, or other mood changes

**Hypersensitivity Reactions (Including anaphylaxis)**
- Healthcare providers should be aware of the risk of hypersensitivity reactions, which may present as infusion reactions, and monitor patients closely
- Some patients received pre-medication; however, there is insufficient evidence to determine whether pre-medication diminishes the frequency or severity of these reactions
- Patients should be informed of the signs and symptoms of a hypersensitivity reaction and instructed to seek immediate medical care should a reaction occur
- In clinical trials, hypersensitivity reactions, including anaphylaxis, were reported
- In the event of a serious hypersensitivity reaction, discontinue BELIMUMAB immediately and administer appropriate medical therapy

**Immunization**
- Live vaccines should not be given for 30 days before or concurrently with BELIMUMAB
- BELIMUMAB may interfere with the response to immunizations

**Use With Biologic Therapies or Intravenous Cyclophosphamide**
- BELIMUMAB has not been studied in combination with other biologic therapies, including B-cell targeted therapies, or intravenous cyclophosphamide
- Therefore, use of BELIMUMAB is not recommended in combination with these therapies

**USE IN SPECIFIC POPULATIONS**
**Pregnancy:** Category C
- BELIMUMAB should be used during pregnancy only if the potential benefit outweighs the risk
- Women of childbearing potential should use adequate contraception during BELIMUMAB treatment and for at least 4 months after the last dose