

<b>Reference:</b>	FOI.4387.20
<b>Subject:</b>	Lupus
<b>Date of Request:</b>	28 October 2020

**Requested:**

1. How many lupus (SLE) patients have received Rituximab treatment by infusion, since the NICE BSR Guideline for the Management of SLE in Adults was published in October 2017?

I ask because those NICE BSR Guidelines state as follows:

*Rituximab for refractory moderate lupus Summary Rituximab can be prescribed and reimbursed in the UK currently according to the NHS England 2013 Interim Clinical Commissioning Policy Statement for rituximab in adult SLE patients [267] who have two or more systems with BILAG B scores; or have severe BILAG A level disease activity, using the BILAG-2004 index [268, 269]; or have a SLEDAI-2 K score [270] >6 if they have failed two or more immunosuppressive agents (due to inefficacy or intolerance), at least one of which must be MMF or CYC; or need unacceptably high doses of steroids to achieve lower level of disease activity.*

*The patients must be managed in conjunction with a specialist centre for lupus and be entered in to the BILAG Biologics Register for standardized reporting of outcome (see Fig. 1 flowchart for eligibility and response criteria). This is essential for providing more open-label data in a prospective study with control patients treated with other immunosuppressive therapies, given the failure of the international double-blind, placebo-controlled lupus trials to meet their primary end points, as discussed below (EXPLORER for active non-renal disease [190, 191] and LUNAR for LN [352]). This policy was agreed as a result of the increasing published evidence supporting the efficacy of rituximab in refractory lupus patients, who are likely to differ from those recruited to trials where there was no requirement to have failed conventional therapy.*

2. In the same period, i.e. from 2017 to date, how many lupus patients have been treated with Ciclosporin, tacrolimus or belimumab?
3. Finally, in your last reply dated 30th September 2020, you commented as follows:
 

“The UHB participated in the All Wales BSR Systemic Lupus Erythematosus (SLE) audit and its compliance is above average for most standards for both the Welsh and UK averages. The audit used standards derived from BSR National Institute for Health and Care Excellence (NICE) Guidelines for the Management of Adults with SLE.”

Please provide a link to this audit/report so that we can read it in full, as this is the first time we have heard of such a report.

**Response:**

Hywel Dda University Health Board (UHB) is unable to provide you with the information requested for questions 1 and 2, as it is estimated that the cost of answering your request would exceed the “appropriate level” as stated in the Freedom of Information (Fees and Appropriate Limit) Regulations 2004. The “appropriate level” represents the estimated cost of one person spending 18 hours or (2 ½ working days) in determining whether the UHB holds the information, and locating, retrieving and extracting the information.

In order to provide you with the information requested, the UHB would need to undertake a manual trawl of all Lupus patient records, to identify any information that fulfils your request. Whilst the UHB could identify the number of prescriptions dispensed for the above named medications from the pharmacy databases, it is not possible to identify the condition these were used to treat without cross referencing against the medical records.

Therefore, for questions 1 and 2, the UHB is therefore applying an exemption under Section 12 of the Freedom of Information Act 2000, which provides an exemption from a public authority's obligation to comply with a request for information, where the cost of compliance is estimated to exceed the appropriate limit.

3. The UHB confirms that the Systemic Lupus Erythematosus (SLE) audit is ongoing and is commencing a second cycle. On completion of the second cycle, the complete audit will be made publicly available.

This information is intended for future publication and is therefore exempt under Section 22 of the Freedom of Information Act 2000. Section 22 can be applied when there is a clear intention to publish the information requested at the time the request was received.

The SLE audit report will be published on the British Society for Rheumatology (BSR) audit webpage and can be accessed via the link below:

<https://www.rheumatology.org.uk/practice-quality/audits/lupus>