This letter is intended for healthcare professionals managing patients receiving Benlysta▼ (belimumab).

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21st May 2020

Re: Short-term availability of belimumab pre-filled pen formulation for subcutaneous (SC) administration for existing patients receiving belimumab solution for injection intravenous (IV) administration during COVID-19 pandemic in the UK.

Dear Healthcare Professional,

In response to the COVID-19 pandemic, I am writing to inform of you of important changes GSK has made to allow the short-term provision (minimum 3 months) of the SC formulation of belimumab via a pre-filled pen for appropriate patients currently receiving the IV formulation of belimumab solution for injection within the UK. Following the pandemic, patients receiving the SC formulation will need to transition back to the IV formulation.

Background information

- GSK acknowledges the current challenges being faced by the NHS in dealing with the COVID-19 pandemic and more specifically, Rheumatologists managing patients with systemic lupus erythematosus (SLE) who have been categorised as very high/high risk individuals.
- GSK is aware that the '*COVID-19 rapid guideline for rheumatological autoimmune, inflammatory and metabolic bone disorders*'[1] published by National Institute for Health and Care Excellence (NICE) on 3rd April recommends assessing whether patients receiving a biologic intravenously can be changed to a SC formulation e.g. belimumab.
- Belimumab pre-filled pen formulation for SC administration received marketing authorisation in Europe in November 2017 and is indicated as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus with a high degree of disease activity (e.g. positive anti-dsDNA and low complement) despite standard therapy. **Please note the SC formulation is currently not indicated for patients <18 years old.**
- The SC formulation has not yet been appraised and recommended for use by NICE.

Changes GSK are making during COVID-19 pandemic

- In line with published NHS and NICE guidance, GSK has agreed with the Medicines and Healthcare products Regulatory Agency (MHRA) and NHS England to temporarily make available a foreign European pack of belimumab pre-filled pen formulation for SC administration, to support existing patients receiving belimumab intravenously and to minimise the need to attend hospital on a monthly basis, where appropriate.
- It is the responsibility of the treating physician to assess whether existing patients receiving IV belimumab should be changed to the SC formulation.

Duration of supply

- In agreement with MHRA and NHS England, GSK will review the need to continue supply of the SC formulation after 3 months.
- NICE will be appraising the SC formulation after the COVID-19 pandemic period is over and will aim to publish guidance in Q2/Q3 2021.
- Following the COVID-19 pandemic, patients will need to transition back to the IV formulation until GSK receives an outcome from the NICE appraisal of the SC formulation.

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Important information on the belimumab (Benlysta) pre-filled pen for subcutaneous injection

- Please refer to the Summary of Product Characteristics attached (last revised 21st of October 2019) before prescribing.
- The pre-filled pen should be used for subcutaneous injection only. Each 1-ml pre-filled pen contains 200 mg of belimumab. The recommended dose is 200 mg once weekly, administered subcutaneously. There is no weight-based dosing requirement with the pre-filled pen as compared to the IV formulation.
- Based on the availability of supply, the packs will either contain 1 x pre-filled pen, 4 x pre-filled pens or 12 x pre-filled pens.
- The recommended injection sites are the abdomen or thigh. When injecting in the same region, patients should be advised to use a different injection site each week; injections should never be given into areas where the skin is tender, bruised, red, or hard.
- Comprehensive instructions for patients on the administration of belimumab pre-filled pen for SC administration is contained within the patient information leaflet included in the pack.

Actions for healthcare professional

- You should consider whether it is appropriate to transition your patients currently receiving belimumab solution for injection intravenously to the belimumab pre-filled pen formulation for SC administration.
- When transitioning patients, the first SC injection should be administered 1 to 4 weeks after the last intravenous dose.
- It is recommended that the first SC injection of belimumab should be under the supervision of a healthcare professional in a setting that is capable to manage hypersensitivity reactions, if required. You must provide patients with proper training in subcutaneous technique and education about signs and symptoms of hypersensitivity reactions. A patient may self-inject, or the patient caregiver may administer belimumab after you determine that it is appropriate.
- For patients transferred onto the SC formulation, please continue to enter data into the BILAG- BR registry at the required time intervals for the IV formulation.

Materials available to support patients

- GSK has developed materials that will be made available to healthcare professionals in specialist rheumatology centres to support patients who are transitioning to the alternative formulation:
    - A letter for patients included with the pack of pre-filled pen(s) (THIS MUST BE PROVIDED TO ALL PATIENTS TRANSITIONING FORMULATION)
    - A URL link to ‘How to Use Belimumab Pre-filled Pen’ video
    - A PDF copy of ‘Instructions to Use’ training guide for healthcare professionals to pass on to the patient

Adverse Drug Reactions (ADRs)

- ▼ This medicinal product is subject to additional monitoring and will allow quick identification of new safety information.
- Healthcare professionals are encouraged to report any suspected ADRs to the MHRA through the Yellow Card Scheme.
- It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.
- Alternatively, prepaid Yellow Cards for reporting are available:
    - by writing to FREEPOST YELLOW CARD (no other address details necessary)
    - by emailing yellowcard@mhra.gov.uk
    - at the back of the British National Formulary (BNF)
    - by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
    - or by downloading and printing a form from the Yellow Card website.
- Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.

Contacts for further information or questions

If you would like a member of the GSK medical team to discuss the content of the letter with you in more detail, please contact:

Dr. Roshni Patel

Medical Head, Benlysta

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Susan Michael

Medical Science Liaison

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Alternatively, for medical information enquiries please email ukmedinfo@gsk.com or call 0800 221 441 (option 4). 8:30am to 5:30pm GMT Monday - Friday. An out of hours service is also provided for emergencies which goes to an external provider outside of the times stated.

Yours sincerely,

Dr Karen Mullen MBBS MRCP MFPM

Country Medical Director, GSK UK & Ireland

Reference

1. https://www.nice.org.uk/guidance/NG167, Accessed on April 2020